

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/27/2020 8:41:48 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: b5 follow-up

Just got off the phone with [REDACTED] b5 –they contacted us as I mentioned on one of our morning calls last week. [REDACTED] b5

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 3/26/2020 7:59:05 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Seen this article in BioCentury?

I agree. Before you send anything out, it may be good to check with them.

From: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Sent: Thursday, March 26, 2020 3:56 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Subject: RE: Seen this article in BioCentury?

No, I have not, Francis. Sounds like a somewhat well-kept secret from the article (well, until now). I would imagine Mikael Dolsten or Paul Stoffels would have to know something about it, however.

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Thursday, March 26, 2020 3:49 PM
To: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Cc: Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Subject: Seen this article in BioCentury?

Hi David,
Have you heard any noises about this pharma effort?
Francis

Pharmas on one page with action plan to solve COVID-19 together
BIOCENTURY IS PROVIDING THIS STORY FOR FREE GIVEN THE URGENT NEED FOR INFORMATION ABOUT THE COVID-19 CRISIS.
BY C. SIMONE FISHBURN, EDITOR IN CHIEF | MAR 25, 2020 | 9:17 PM EDT
A grand-scale behind-the-scenes effort by the pharmaceutical companies is under way to expedite the creation of therapies and vaccines to treat COVID-19.

According to the participants who spoke with BioCentury under conditions of anonymity, R&D heads from at least 10 companies have been gathering several times a week, setting in motion an action plan to use their top talent in different disciplines to produce an industry-wide response, the likes of which haven't been seen since the private sector's coordinated contribution during World War II.

Regulatory heads and manufacturing heads have been holding meetings as well, coordinating to minimize duplication of effort, streamline work and advance efficient testing of compounds and vaccines.

The R&D group is creating working principles to accelerate new COVID-19 therapies and vaccines agnostic to their market potential, eliminating bureaucratic and technical or scientific barriers, and focusing on filling gaps not adequately filled by other initiatives and which the consortium is uniquely suited to address.

The pharma group's leaders also intend to offer resources to biotechs and academic groups pursuing countermeasures who may not want to join the effort but could benefit from expert guidance.

Flying the plane as they build it, the collaborators intend to create a clearing house of ideas for testing of molecules and vaccines, with working groups to vet the ideas and expedite testing on the most promising via clinical or preclinical testing.

According to the participants who spoke to BioCentury, the structure will probably evolve over time. Currently, the model involves five working groups, for clinical phase repurposing, novel small molecule antivirals, novel antibodies, preventive vaccines and preclinical repurposing. Each will be headed by a pharma R&D executive and will be responsible for prioritizing potential compounds and specifying actions.

Two platform groups will integrate across modalities: a clinical trial acceleration group and a data sharing group.

"This is not a time to think about proprietary information or IP or margins. We need to break down the barriers and solve the problem," said one participant involved in the consortium.

Further analysis of the coronavirus crisis can be found at <https://www.biocentury.com/coronavirus>.

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
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To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Seen this article in BioCentury?

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Cc: Freire, Maria (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: Seen this article in BioCentury?

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Sent: Thursday, March 26, 2020 3:49 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Freire, Maria (FNIH) [T] <[REDACTED]> **b6**
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Further analysis of the coronavirus crisis can be found at <https://www.biocentury.com/coronavirus>.

Sent: 6/3/2020 11:26:40 PM
To: Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]
CC: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Rashid, Kamilah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce52e57bb74034834aa8660b5c8677-rashidkl]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration
Attachments: 2020-06-03_COVID-19PortalSubmissions.xlsx

Hi Christine,

Please see the attached agents received by the COVID-19 portal May 23-May 29 and were selected by the NIH SMEs to move forward for ACTIV. 54 submissions were received in total.

We have a training scheduled tomorrow to learn more about the dashboard NCATS has funded. I still haven't quite yet wrapped my head around how all these things will be tracked. Francis is interested in knowing how we will be able to track all compounds that come in to the COVID-19 portal that is then shared with RADx, ACTIV, ICs, etc. – what happens to all of them if asked what happened with compound X?

From: Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>
Sent: Monday, June 1, 2020 8:57 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> Cutillo, Christine (NIH/NCATS) [E] <[REDACTED]>
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> Ford-Scheimer, Stephanie (NIH/NCATS) [C] <[REDACTED]>
[REDACTED]; Rashid, Kamilah (NIH/OD) [E] <[REDACTED]>
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

Many thanks – this is just what we need and will be very useful for ensuring that our inventory process is comprehensive. In addition, the way the data are presented is quite good and will help us in our efforts to determine how to do that broadly.

All best,

Chris

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Sunday, May 31, 2020 8:48 PM
To: Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>; Cutillo, Christine (NIH/NCATS) [E] <[REDACTED]>
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]>; Ford-Scheimer, Stephanie (NIH/NCATS) [C] <[REDACTED]>
[REDACTED]; Rashid, Kamilah (NIH/OD) [E] <[REDACTED]>
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Chris and Christine,

Got it! Attached is the spreadsheet of emails received between early March and late May. With the [NIH COVID-19 Candidates and Technologies Portal](#) now live, all emails relevant to ACTIV are being routed there for submission and we've only had one round of review by the NIH COVID portal review group for inquiries received May 14-22 – please see

2nd attachment. The review group received a total of 58 submissions, 15 were determined to have potential – 8 of which are relevant to ACTIV.

Christine – I will cc you when we receive these each week. The 2nd attachment will provided an idea of the data fields used for the COVID portal.

We are still working on a process for receiving candidates from BARDA that have been reviewed by NIH staff who attend the BARDA held CoronaWatch meetings. Hopefully we can easily integrate those into a single spreadsheet to be shared. I've been working closely with Kamilah on Tara's team with this and we've discussed some of the questions outlined below –cc'ing Kamilah in case she has anything to add.

Thanks,
Ashley

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Sunday, May 31, 2020 11:18 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Cutillo, Christine (NIH/NCATS) [E] [b6] >; Adam, Stacey (FNIH) [T] [b6] >; Ford-Scheimer, Stephanie (NIH/NCATS) [C] [b6]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

Thank you for all your efforts and sorry for the delay in getting back to you; as you know, ACTIV has been busy!

Just want to clarify the portals issue. You're right that Larry has brought Deloitte in to do a larger assessment of COVID informatics needs since many ICs have asked for solutions; he and Susan G are leading that and there is a WG of us ICDs that will help. The immediate portal need is for ACTIV, to allow their prioritization teams, coordinated by Joe Menetski and Stacey Adam at FNIH, to have all the possible assays and agents to consider for inclusion. Christine Cutillo is working very closely with the FNIH and Deloitte teams to bring all the entries from many different portals into a single database. We want to be sure to include the entries that the OD portal is getting.

If you are sending all the submissions from the OD portal to FNIH already, the issue may have been solved indirectly already since the combined NIH-FNIH-Deloitte group has the OD entries. But it does appear quite odd for the NIH IC partners on ACTIV (coordinated by Christine Cutillo) to not receive NIH data from the OD, but rather have to get it from FNIH. Hence my request to simply get the information directly from you. To prevent any entries from falling through the cracks, pls begin copying Christine on the information you share with FNIH each week.

Hope this makes sense. Thanks,

Chris

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 20, 2020 7:12 PM
To: Cutillo, Christine (NIH/NCATS) [E] [b6] Adam, Stacey (FNIH) [T] < [b6] Anderson, James (NIH/OD) [E] [b6] >
Cc: Austin, Christopher (NIH/NCATS) [E] [b6] >; Santangelo, George (NIH/OD) [E] [b6] Ford-Scheimer, Stephanie (NIH/NCATS) [C] < [b6] Gladman, Jordan (NIH/OD) [E] [b6] >
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

There have been a few updates since the note from Chris on Sunday and I want to clarify a few things.

- We have not received any spreadsheets from BARDA with data fields – one of the NIAID POs who is a reviewer for the BARDA CoronaWatch meetings shared a PDF short list of compounds for ACTIV Tx clinical WG to consider – this is what I shared on Friday.
- The spreadsheet OD has managed prior to the launch of the COIVD portal only contains emails (contact info, brief descriptor i.e. vaccine, preclinical interest, etc.) Dr. Collins has received as it relates to ACTIV. We have shared these with FNIH each week to sort and share relevant information with the WGs. ES has sent a standard response to those emails and in some cases FNIH has followed up when relevant. I think only a handful may have been fully useful and fleshed out.
- Tara's team is leading the NIH portal efforts – yes, data fields are closely aligned with BARDA. Also, Tara's team has a review process for queries received through this portal and would have the spreadsheet of data fields you are looking for – it may be a good idea to touch base with Tara and her team to ensure the efforts outlined below are aligned.
- **As of yesterday, my understanding was Dr. Tabak made a decision to coordinate these efforts via a small IC data group and next steps are to bring in PM from Deloitte as you've indicated below to access all of the needs including RADx, ACTIV, and others before making a final decision to merge information from all portals. My take on this was to pause for the moment but I defer to Chris on the action items below.**

I hope this is useful.

Best,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] [REDACTED] b6
Sent: Wednesday, May 20, 2020 3:37 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED] b6>; Parker, Ashley (NIH/OD) [E] [REDACTED] b6>; Anderson, James (NIH/OD) [E] [REDACTED] b6
Cc: Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6>; Santangelo, George (NIH/OD) [E] <[REDACTED] b6> Ford-Scheimer, Stephanie (NIH/NCATS) [C] [REDACTED] b6>
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Dear All,

Wanted to provide you with an update – we have been working with Andrew Derr (Deloitte NIH contract) to get someone by tomorrow/end of the week to start working on this. More detailed steps are included below in addition to a few questions. For clarification – which spreadsheet/database contains the appropriate data fields that should be propagated/mapped for each of the others (e.g., the BARDA submissions or the ACTIV compound spreadsheet)? I believe the NIH portal was built based on the BARDA submission data fields, but if we're ultimately aiming to connect to the ACTIV compound spreadsheet then potentially we should build toward that now when connecting these unsolicited submissions. Also, where do the submissions received via the NIH portal live and/or will a spreadsheet be sent at some periodicity? I apologize if these are questions that have already been addressed, but I haven't received that information yet.

Best,
Christine

1. Merge relevant information from all portals mapped to consistent data fields into the NIH db ("relevant" means submissions relevant to the ACTIV process; some NIH portals will contain COVID-related but not ACTIV-relevant entries)
 - a. BARDA submissions – ***is this the template of data fields that all others should be aligned with or should they be aligned with the data fields contained within the ACTIV compound spreadsheet?***
 - b. OD received submissions (prior to implementation of portal) – ***Ashely***, do you have this spreadsheet and have the data fields already been aligned with BARDA and/or the NIH portal?
 - c. NIAID submissions – spreadsheet provided by Alan Embry (contact him to ensure on same page); data fields need to be mapped/aligned
 - d. NCATS submissions – data fields need to be mapped/aligned
2. Eliminate duplicate entries (sent by the same person to multiple portals)
 - a. Via name/email matching
3. Send email to those not submitted through the NIH portal
 - a. Permission to integrate into ACTIV prioritization
 - b. Fill out survey – ***either compound RedCap survey or NIH portal depending on answer to initial question – thinking it's the former?***
4. Collate all into single db/spreadsheet for ACTIV/TransNIH use
5. Set up process for updating submissions received via NIH portal and other sources
 - a. ***Where do the submissions received via the NIH portal live and/or will a spreadsheet be sent at some periodicity?***
 - b. ***Has an email been sent out alerting folks at NIH to direct external inquiries to this portal or do we need to set up a process for receiving new submissions from e.g., NIAID?***

Christine Cutillo, MMCI
 Special Assistant to the Director
 Office of the Director
 National Center for Advancing Translational Sciences
 National Institutes of Health

b6

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Sunday, May 17, 2020 12:37 PM
To: Adam, Stacey (FNIH) [T] b6; Parker, Ashley (NIH/OD) [E] b6 >; Cutillo, Christine (NIH/NCATS) [E] b6; Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
 ; Anderson, James (NIH/OD) [E] b6; Santangelo, George (NIH/OD) [E]
 b6
Subject: FW: BARDA Corona Watch | Therapeutic Candidates for Consideration

All,

We made good headway last week on a strategy to eliminate redundant entries from different submission portals to enable a complete and nonredundant list of entries to be provided to Stacey's group for wave 2 and wave 3 prioritization. The list from BARDA enclosed, and the analysis Stacey did on it, is just the kind of information we have, or need to extract, from the NIAID portal, NCATS portal, Bldg 1 portal, intramural portal, and nonpublic OPA db. The steps defined are:

1. Merge relevant information from all portals into the NIH db ("relevant" means submissions relevant to the ACTIV process; some NIH portals will contain COVID-related but not ACTIV-relevant entries)
2. Eliminate duplicate entries (sent by the same person to multiple portals) by name/email matching

3. Depending on whether the portal required the submitter to grant permission for sharing internal to NIH and/or with ACTIV (latter, non-NIH for evaluation purposes only, under NDA), send submitter an email asking for such permission to be granted, and
4. Depending on whether the submitter included the fields needed by Stacey's group for initial evaluation, in same email ask the submitter to supply the missing information
5. Collate responses and deliver to Stacey.

Christine, please devise a sequential workflow and enlist those you need for help.

Many thanks to all the portal owners for helping to create a filter funnel that will get the relevant information to ACTIV.

Chris

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Saturday, May 16, 2020 11:05 AM
To: Freire, Maria (FNIH) [T] <[b6]>; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] <[b6]>; Tabak, Lawrence (NIH/OD) [E] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria,

Of the top three candidates we selected: Abatacept (CTLA-IgG1 Fusion), Cenicriviroc (CCR2/5 inhibitor), and Infliximab (TNF-alpha antagonist). Only the TNF inhibition seems to appear on the BARDA list.

Of our top 39 candidates that got scored, many MOAs were working to address some of the same issues that those on the BARDA list seem to target, such as anticoagulants, though those we reviewed and selected were largely already available in hospitals so they could be easily and quickly deployed for the NHLBI/NINDS trial. BARDA's anticoagulants seem to be next generation and working through slightly different MOAs. Also, we had number of anti-inflammatory targeting MOAs on our list that don't appear on the BARDA list, such as anti-IL17, RASP inhibition, PDE4 inhibition, GSMF inhibition, and others. But again, both groups trying to get at the same issue, just through different points in the inflammation pathway. The one thing I notice is the BARDA list only seems to have 1 antiviral on their list, whereas we have about 9, and while we didn't prioritize them first, we did think some would likely be high priority for our next wave of trials with a slightly different design.

Again, I hope this is helpful.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Freire, Maria (FNIH) [T] <[b6]>
Sent: Saturday, May 16, 2020 10:51 AM
To: Adam, Stacey (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];

Lane, Cliff (NIH/NIAID) [E] < [REDACTED] b6 Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6
Anderson, James (NIH/OD) [E] [REDACTED] b6 >; Wholley, David (FNIH) [T]
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Thank Stacey- very helpful. How about the converse: are there MOA on the WG list that are not on this one? M.

From: "Adam, Stacey (FNIH) [T]" [REDACTED] b6
Date: Saturday, May 16, 2020 at 9:40:55 AM
To: "Freire, Maria (FNIH) [T]" [REDACTED] b6, "Collins, Francis (NIH/OD) [E]" [REDACTED] b6
Cc: "Parker, Ashley (NIH/OD) [E]" [REDACTED] b6, "Tabak, Lawrence (NIH/OD) [E]" < [REDACTED] b6
"Lane, Cliff (NIH/NIAID) [E]" < [REDACTED] b6, "Austin, Christopher (NIH/NCATS) [E]" [REDACTED] b6
"Anderson, James (NIH/OD) [E]" [REDACTED] b6 >, "Wholley, David (FNIH) [T]" [REDACTED] b6 >
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria and Francis,

As these compounds largely did not have information in the public domain for ongoing trials or major preclinical experiments in SARS-CoV-2 when we did our first pull 5 weeks ago, most, if not all, would not have been on our list.

However, looking at the mechanisms of action (MOA), we did have a number of agents that have same or similar MOAs, including IL-6 inhibition (3 agents on our review list) and JAK/STAT inhibitors (4 on our list). Both of these classes our group chose not to select for the first large confirmatory trial we were designing because their MOAs were being studied in well designed trials by other groups.

There are some MOAs that were not on our original list, such as IL-15 inhibition, though we did have many other IL inhibitors, including IL-1, 6, and 17. The Syk inhibitors are also a new MOA that did not appear in the first 170 of clinically ready agents.

I hope this information helps.

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Freire, Maria (FNIH) [T] [REDACTED] b6
Sent: Saturday, May 16, 2020 10:03 AM
To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6
Cc: Parker, Ashley (NIH/OD) [E] [REDACTED] b6; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6;
Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6
Anderson, James (NIH/OD) [E] [REDACTED] b6 >, Wholley, David (FNIH) [T] [REDACTED] b6, Adam,
Stacey (FNIH) [T] < [REDACTED] b6
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Good morning Stacey. Could you please take a look and let us know? Many thanks, M.

On May 16, 2020, at 8:46 AM, Collins, Francis (NIH/OD) [E] < [REDACTED] b6 > wrote:

Interesting. Would the therapeutics on this list have been on the list of 170 that the Therapeutics Clinical WG was prioritizing?

FC

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Friday, May 15, 2020 2:49 PM
To: Collins, Francis (NIH/OD) [E] <b6>, Tabak, Lawrence (NIH/OD) [E] b6 >; Lane, Cliff (NIH/NIAID) [E] b6 >; Austin, Christopher (NIH/NCATS) [E] b6 >; Anderson, James (NIH/OD) [E] b6 >; Wholley, David (FNIH) [T] b6 >; Freire, Maria (FNIH) [T] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi all,

Attached is a list of compounds shared by one of NIAID's program officers, Steve Smiley who is a reviewer/participant assigned to the **therapeutics Tech Watch (now CoronaWatch) meetings** at BARDA. Steve indicated they have ~10 meetings per week and there are other NIAID experts who join these. He suggested NIH reps who attend the BARDA meetings could assist with sharing compounds with ACTIV – recent focus has been on therapeutic products for infected outpatients for the DAIDS ACTG network but he indicated many products are better suited to phase 2 testing in hospitalized patients.

Steve also suggested we develop a short script for the NIH POCs who attend the BARDA Corona Watch meetings and use this as an opportunity to inform companies about ACTIV. We could link them to our vetting process (i.e. new portal) and/or feed them directly to the working groups. It seems prior to ACTIV, NIAID has used these Corona watch meetings to look for opportunities that would be useful for NIAID networks – Cliff likely has more insight here. The opportunity to expand and be inclusive of ACTIV seems like the right path and an opportunity to stay connected with what comes through BARDA.

Would this be something of interest to the group?

Thanks,
Ashley

From: [REDACTED]
Sent: 7/24/2020 1:19:26 AM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Re: ACTIV graphics 1.0

That's fine.

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [REDACTED]

On Jul 23, 2020, at 9:14 PM, Menetski, Joseph (FNIH) [T] <[REDACTED]> wrote:

Yup, oops, sorry. I just sent it to Francis and cc'd you.

Maria suggested sending to Francis, too.

Joe

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Thursday, July 23, 2020 9:11 PM
To: Menetski, Joseph (FNIH) [T] <[REDACTED]>
Cc: Tountas, Karen (FNIH) [T] <[REDACTED]>
Subject: Re: ACTIV graphics 1.0

Has Maria had a chance to review?

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [REDACTED]

On Jul 23, 2020, at 8:54 PM, Menetski, Joseph (FNIH) [T] <[REDACTED]> wrote:

I will take care of it, and then we could send this to Francis as a first see. Ashley, is it OK for me to send it on behalf of us?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Thursday, July 23, 2020 8:29 PM
To: Tountas, Karen (FNIH) [T] <[REDACTED]>
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]>
Subject: Re: ACTIV graphics 1.0

Hi Karen,

I've included other parameters in the excel sheet but not on the graphic — not sure what exactly what you have in mind or if I have the "Karen" visual skills! Would you like

to add a visual with the parameters to the current slide? Please feel free to edit as needed.

Thanks,
Ashley

On Jul 23, 2020, at 8:13 PM, Tountas, Karen (FNIH) [T] b6 wrote

I agree, this is a great start and agree with sharing the grid only. We had talked about listing other potential parameters on the side of the grid to facilitate discussion of what they want tracked and portrayed - e.g. enrollment targets, IND status, etc.

Thanks,
Karen

From: "Menetski, Joseph (FNIH) [T]" b6
Date: Thursday, July 23, 2020 at 6:34:41 PM
To: "Parker, Ashley (NIH/OD) [E]" b6 "Tountas, Karen (FNIH) [T]" b6
Subject: RE: ACTIV graphics 1.0

Thank you Ashley, this is a great start. I agree that the excel file is not for the war room, but the list of trial data is exactly what we need for the discussion.

I will share with Maria and then get back to you.

Joe

From: Parker, Ashley (NIH/OD) [E] < b6 >
Sent: Thursday, July 23, 2020 6:25 PM
To: Menetski, Joseph (FNIH) [T] b6 >; Tountas, Karen (FNIH) [T] b6
Subject: RE: ACTIV graphics 1.0

Hi Joe and Karen,

Please see the attached draft grid of ACTIV/NIH trials with the attached spreadsheet. Included in tab 3 are additional types of trial information that can be gathered – I do not necessarily recommend sharing the spreadsheet with the war room but using for our purposes.

Edit as you see fit and please let me know if you'd like to make edits. It may be a good idea for me to send to FC tonight for review, prior to sharing broadly with the war room group tomorrow morning.

I standby for any edits – after dinner of course!

Thanks,
Ashley

From: Menetski, Joseph (FNIH) [T] b6
Sent: Thursday, July 23, 2020 8:52 AM
To: Parker, Ashley (NIH/OD) [E] < b6
Subject: RE: ACTIV graphics 1.0

Thank you Ashley. Karen, terrific progress.

From: Parker, Ashley (NIH/OD) [E] < b6
Sent: Thursday, July 23, 2020 8:51 AM
To: Tountas, Karen (FNIH) [T] b6
Cc: Menetski, Joseph (FNIH) [T] b6
Subject: RE: ACTIV graphics 1.0

I will jump off of the Vaccines WG meeting to talk then.

Thanks,
Ashley

From: Tountas, Karen (FNIH) [T] b6
Sent: Thursday, July 23, 2020 8:49 AM
To: Parker, Ashley (NIH/OD) [E] b6
Cc: Menetski, Joseph (FNIH) [T] b6
Subject: RE: ACTIV graphics 1.0

Ashley, would 2-2:30 work for you?

From: Menetski, Joseph (FNIH) [T] b6
Sent: Thursday, July 23, 2020 8:48 AM
To: Parker, Ashley (NIH/OD) [E] b6 . Tountas,
Karen (FNIH) [T] b6
Subject: RE: ACTIV graphics 1.0

I am busy up to about 12:30... Sorry. Any time after 2?

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Thursday, July 23, 2020 8:35 AM
To: Menetski, Joseph (FNIH) [T] b6 >; Tountas, Karen
(FNIH) [T] b6
Subject: RE: ACTIV graphics 1.0

I'm available now or 30 mins and then free again at 10am.

Thanks,
Ashley

From: Menetski, Joseph (FNIH) [T] < b6
Sent: Thursday, July 23, 2020 8:32 AM
To: Parker, Ashley (NIH/OD) [E] b6 . Tountas,
Karen (FNIH) [T] b6
Subject: RE: ACTIV graphics 1.0

Lots of great comments.

The goal was to compare therapies, with populations, so I think this y axis on the dot plot is good, but could be separated more, I think.

Can we have another short call? I think there are some things that I am missing. I am not sure the phase of the trial is something that needs to be prominent, more important is the type of therapeutic and the end date.

This may need to be a series of graphs and then they can pick from them??

Joe

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, July 22, 2020 7:57 PM
To: Tountas, Karen (FNIH) [T] b6 ; Menetski, Joseph (FNIH) [T] b6
Subject: RE: ACTIV graphics 1.0

Hi Karen,

This looks like a great start! A few minor comments/thoughts and responses to your questions:

1. Should we keep all drug therapies separate? i.e. place antivirals in a bucket of its own? We would see a salmon colored dot twice. Maybe also include a bucket for other therapies which will be blank for the moment and include various vaccine treatment options (mRNA, protein, etc) ?
2. I think the current model clearly indicates which compounds are being tested in the various population groups -- if this was the original request or intent, Joe can confirm based on conversations with Maria and the war room. Current graphic doesn't make it clear to know which phase(s) the trials are in although I see the reference target on the bottom right. We discussed the option of showing the trial phases on the x-axis with the patient populations on the y-axis, and compounds on the z-axis but I do not have a preference here.
3. Should we add additional population groups: emergency department, hospitalized ventilated vs. hospitalized non-ventilated, mild/moderate/severe disease? Only a thought, do we want to track recovery and include recovered patients eventually in a separate graphic?
4. Should all of the dots be the same size (the salmon dot looks smaller but maybe its my vision!)
5. ACTIV-2 -- they are starting with their phase 2 study. Subjects will be outpatient -- is that outpatient asymptomatic or symptomatic or both? I would assume outpatient symptomatic but Stacey can confirm?
6. ACTIV-4 -- they have three protocols. I think we should track each separately. Your thoughts? Agree we should track them

separately and they will launch/start enrollment at different times.

1. Need list of agents to be tested: I am happy to ask NHLBI contacts for this information unless we prefer to start with Stacey?
2. Need IND status: In-hospital was approved by the DSMB last week. Prehospital will be reviewed by the DSMB today 7/22 I do not know the IND status of the post hospitalization—Stacey will likely have information
7. Need target enrollment numbers for each – I just stuck in numbers for illustrative purposes (see above) I have not seen the target enrollment numbers for ACTIV1-4, should we ask Stacey? I am happy to ask NHLBI for ACTIV-4 if needed
8. Need anticipated launch dates for each trial I've only see launch weeks: ACTIV 2-4 week of July 27 (ACTIV-4 inpatient week of July 27, outpatient and post-hosp. is unclear to me) and ACTIV 1- mid August
9. Enrollment tracker looks good to me! No comments at the moment

Please let me know if we should start with Stacey for the remaining responses or if you prefer I contact NHLBI.

Thanks,
Ashley

From: Tountas, Karen (FNIH) [T] b6
Sent: Wednesday, July 22, 2020 5:27 PM
To: Menetski, Joseph (FNIH) [T] <b6> . Parker, Ashley (NIH/OD) [E] b6
Subject: ACTIV graphics 1.0

Hi Joe and Ashley,

I have been thinking about graphic representation for the ACTIV CT details and still like what we had talked about this morning, but excel does not all creation of x/y/z scatter plots (or at least I cannot figure it out), so...

I made two plots:

1. one for information about each trial (I'm a little iffy on this plot, it needs something ..).
2. and the other to track the status of enrollment versus the target (all numbers are just for demo – I don't have the real enrollment targets and obviously no subjects have enrolled yet.).

See what you think.

Of note, excel would not let me change the axis labels so these are just text boxes – not sure what was going on but...

<image001.png>

<image001.png>

Some of the information in the attached spreadsheet needs a bit more granularity as detailed below – do either of you have the answers?

1. ACTIV-2 – they are starting with their phase 2 study. Subjects will be outpatient – is that outpatient asymptomatic or symptomatic or both?
2. ACTIV-4 – they have three protocols. I think we should track each separately. Your thoughts?
 1. Need list of agents to be tested
 2. Need IND status
3. Need target enrollment numbers for each – I just stuck in numbers for illustrative purposes (see above)
4. Need anticipated launch dates for each trial

Best,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

b6 fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
<image003.jpg> <image002.jpg> <image005.jpg> <image003.jpg>

Donate to the FNIH's Pandemic Response Fund to combat COVID-19:
fnih.org/pandemic

<image007.png>

Confidentiality Notice

Sent: 4/28/2020 10:37:39 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: TIME SENSITIVE - WH Slides updated

Thanks, Jill Francis – I'm looking back at the ACTIV press release 4/17 and noticed we had CDC listed as a partner. Should we need to add them to the partner slide as well or not this time?

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, April 28, 2020 5:10 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: TIME SENSITIVE - WH Slides updated

Sent: 4/27/2020 5:02:49 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Public-private research collaboration

Victoria Davey at the VA has been added to the Clinical Capacity Working group – title pasted below.

CRADO for Epidemiology and Public Health
US Department of Veterans Affairs
Washington, DC

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, April 27, 2020 12:41 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Public-private research collaboration
Importance: High

What have we already done to incorporate VA into ACTIV?
FC

From: Clancy, Carolyn [REDACTED] **b6**
Sent: Monday, April 27, 2020 9:02 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] **b6**
Cc: Tabak, Lawrence (NIH/OD) [E] [REDACTED] **b6**
Subject: Public-private research collaboration
Importance: High

Francis,

I read about the initiative / collaboration being led under the auspices of FNIH.

In the spirit of 'we're from the government and here to help', I am writing to express my team's enthusiasm for being a vital participant (we do have 170 medical centers and close to 9 million patients enrolled).

We are collaborating now with NIAID and others – and I am most excited to report that Dr. Ramoni has driven a year long initiative to streamline VA participation in clinical trials.

Many thanks in advance for your consideration.

Hope you and your loved ones are safe and in good health.

Carolyn. – personal cell [REDACTED] **b6**

Carolyn M Clancy, MD
Assistant Undersecretary for Health
Discovery, Education and Affiliated Networks
Department of Veterans Affairs
810 Vermont Ave NW
Washington, DC 20420

Assistant: Alicia Bates b6); b6

Sent: 7/20/2020 3:10:06 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Time Sensitive: Dr. Collins' Hever Meeting July 24
Attachments: Draft ACTIV slides Hever COVID Meeting June 242020-sja .pptx

Hi Jill,

We grabbed ice cream yesterday as well but didn't know if was NICD! I actually do not mind the heat and enjoy ever moment before it get's cold out although 108 may be unbearable.

I need to send these slides back to FC – do you have any edits? I'm not a fan of the fonts used here but really have too many things to do!

Thanks!
Ashley

From: George, Jill (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 20, 2020 10:21 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Time Sensitive: Dr. Collins' Hever Meeting July 24

Thanks for the cc!

Hope you're staying cool. I went outside yesterday—but only to jump into an airconditioned car to get ice cream on National Ice Cream Day. 😊
Okay, I also watered the plants on our deck because I couldn't bear watching them fry.
Jill

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 20, 2020 9:49 AM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Cc: George, Jill (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Time Sensitive: Dr. Collins' Hever Meeting July 24

Hi Stacey,

Francis is scheduled to give an ACTIV update to the Hever group this Friday 7/24. Attached are slides he would like to present but he asked that I check with you to confirm if it's OK to share slides 5 and 6 with this group and if there is confidential information that should not be shown to Hever.

Pre-reads are due today – please let me know if slides 5-6 are OK to share or if you have edits. For your reference, I've included the slides we shared with this group for the June update.

Hi Jill – for ease of doing things quickly, I am cc'ing you in case you have any minor visual edits.

Thanks,
Ashley

Ashley Parker, Ph.D.

Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Office of the Director | National Institutes of Health

Tel: b6



National Institutes of Health

Sent: 8/26/2020 3:22:34 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Mar a (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: Letters to leadership of urgent COVID-19 therapeutic trials
Attachments: Letter to ACTIV-2 investigators and institutions final.pdf

Hi David,

As promised, with many thanks to Francis and Janet, attached is the letter for the ACTIV-2 investigators and institutions/sites. Can the FNIH team ensure these get to the right places today?

FYI – Cliff indicated he would take care of ACTIV-3.

Thank you!
Ashley

Sent: 7/17/2020 6:41:14 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
BCC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]
Subject: FW: OD COVID-19 Portal Reviews for ACTIV June 6-June 12
Attachments: 2020-06-15_OD-Portal_forACTIV.xlsx

Please see ACTIV COVID-19 portal submissions received June 6-12th – **9 out of 33 vetted for ACTIV.**

Thanks,
Ashley

Sent: 4/30/2020 2:55:34 PM
To: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Covid-19 Vaccine Project Concept

Hi Abbey,

Thank you for sharing the request. Our NIH team is working with BARDA to develop the portal and we have training scheduled for this afternoon. I will let you know when this is up and running and David will likely share this information with the FNIH team as well.

Thanks,
Ashley

From: Meltzer, Abbey (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, April 30, 2020 10:18 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**; Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Subject: FW: Covid-19 Vaccine Project Concept

Hi Ashley,

Here is another request that we received related to ACTIV.

Just out of curiosity, do you have an update as to when a link to a portal/database will be up and running to collect this information?

Best,
Abbey

Sent: 5/5/2020 4:41:12 PM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolberg]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Rebecca,

I am working through this now and was planning to share with you within the next hour or so before sending to FC tonight. For the questions you've raised in the draft, did you not want me to share this with you before it goes to FC?

I will attached the draft figure and include the additional reference you've provided below

For the table: there are concerns about sharing this information publicly and I think this will be discussed with the leadership group tomorrow.

Thank you,
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, May 5, 2020 12:32 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Cc: George, Jill (NIH/OD) [E] <[REDACTED]>
Subject: FW: Need help on a JAMA article on ACTIV

Hi Ashley,

Just a few follow-up items for the modified version of the JAMA draft that you'll be sending to FC for his review tonight.

Figure. Attached is a draft Figure for FC's review. It is in JAMA's figure style and is adapted from the slide that FC plans to use at the Senate HELP Hearing. Please keep this as a separate file, per JAMA's instructions to authors.

Possible eTable. Once Jill and I receive from you the "short list" of potential COVID-19 therapies proposed for rapid clinical testing, we could create a Table that JAMA editors would likely designate as an eTable for inclusion in Supplementary materials. If we don't receive that info in time to make the Table today, we can work on it tomorrow and send to FC for his review separately.

References. The Science Perspectives article that FC attached to his email this morning should be cited as a reference in the sentence below, as well as added as citation #4 to the References list at the end of the draft. Don't worry about the style of the reference right now.. just insert the authors, title, and put publication TBD.

Sentence: **The Vaccines Working Group** will build a collaborative framework to share insights into natural immunity and vaccine candidate-induced immune response [4].

Hope this helps!
Rebecca

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, May 5, 2020 7:15 AM
To: Kolberg, Rebecca (NIH/OD) [E] <[REDACTED]>; Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED]>; George, Jill (NIH/OD) [E] <[REDACTED]>; Tabak, [REDACTED]

Lawrence (NIH/OD) [E] < [REDACTED] b6 [REDACTED] . Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]

Subject: FW: Need help on a JAMA article on ACTIV

Hi Rebecca,

Thanks for this very nice draft. Since Ashley has already seen a draft of the slides for tomorrow, I'm hoping she can provide the needed updates now. Ashley, can you take a crack at that, and then send me a modified version for me to look at tonight?

I'm also attaching a close-to-final draft of an article on COVID vaccine strategy that will appear next week in the NEJM. It mentions ACTIV rather prominently, and needs to be cross referenced.

FC

From: Kolberg, Rebecca (NIH/OD) [E] < [REDACTED] b6 [REDACTED]

Sent: Monday, May 4, 2020 6:25 PM

To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6 [REDACTED]

Cc: Burklow, John (NIH/OD) [E] [REDACTED] b6 [REDACTED] ; Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED] George, Jill (NIH/OD) [E] [REDACTED] b6 [REDACTED]

Subject: RE: Need help on a JAMA article on ACTIV

Hi Francis,

Attached for your review is a draft of your JAMA article. Don't know if you want to look it over now, or if you'd rather wait for me to revise/update when Ashley or someone else sends me over updates from the Working Group meetings on Wednesday. Makes no difference to me!

In addition to the two key locations where you've noted that updates will be needed, there are a few other "late April" and "early May" mentions of deliverables throughout that we will need to address, probably after the WG meeting. Jill will adapt your second ACTIV slide from the Senate hearing for use as Figure 1 and I'll write a caption. If space allows, we might also propose a Table of the short list of the most promising treatments proposed by the Clinical Therapeutics Working Group.

Thanks,
Rebecca

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6 [REDACTED]

Sent: Sunday, May 3, 2020 4:26 PM

To: Kolberg, Rebecca (NIH/OD) [E] [REDACTED] b6 [REDACTED]

Cc: Burklow, John (NIH/OD) [E] [REDACTED] b6 [REDACTED] ; Parker, Ashley (NIH/OD) [E] < [REDACTED] b6 [REDACTED] >; George, Jill (NIH/OD) [E] [REDACTED] b6 [REDACTED]

Subject: Need help on a JAMA article on ACTIV

Hi Rebecca,

I'm hoping you can quickly dive into assisting with the development of a draft of the article on ACTIV that JAMA has agreed to consider. It's really important that we get something publishable out there for people to see, as ACTIV has come along very quickly and most people don't even know about it.

Attached is a copy of the e-mail from Howard Bauchner where he offers 1400-1500 words and a Figure.

Also attached is an outline – the beginning and end parts are from me, the middle parts from Ashley. Already at 1371 words, I recognize that some details will need to be dropped.

Also attached is a figure that could be used to explain the structure of ACTIV.

Have a look and let me know what you need to proceed. I'd love to get this submitted this week.

Tx, Francis

Sent: 4/28/2020 9:46:25 PM
To: Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]
Subject: RE: ACTIV background slides
Attachments: WH ACTIV 042920 Updated FINAL.pptx

Please see attached slides for Dr. Collins' WH briefing tomorrow -- slide 1 is a updated partnership slide.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Tuesday, April 28, 2020 11:20 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: ACTIV background slides

Sounds great to me, thanks.

On 4/28/20, 11:12 AM, "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> b6 wrote:

Hi Hilary,

Sounds like a great plan. Please see attached slides that were presented at the ACTIV leadership meeting on 4/22. We are in the process of updating slide 2 to include additional partners -- I will share once this is ready.

It may be a good idea to keep the lines of communication open between OD and NIAID to share materials that are presented outside of NIH. If you agree -- we can be the POCs for cross sharing.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Tuesday, April 28, 2020 10:54 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: ACTIV background slides

Thanks Ashley - We anticipate future congressional hearings for ASF and want to make sure messaging is consistent with Dr. Collins. Even just the bullet points from the slides would be fine (and we can make our own visuals)

On 4/28/20, 10:12 AM, "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> b6 wrote:

Hi Hilary,

We have slides that Francis has presented to the leadership group and we are editing a few slides for the WH briefing tomorrow. I think we can share some that we have but will need to know who will be using them and for what platform to ensure we are not duplicating.

Happy to chat if needed.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Tuesday, April 28, 2020 10:06 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: FW: ACTIV background slides

Ashley, do you have slides that would fit the bill?

On 4/28/20, 10:05 AM, "Wholley, David (FNIH) [T]" <[REDACTED]> b6 wrote:

Hilary, could I ask that you please contact Ashley Parker in OD about this?

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Tuesday, April 28, 2020 9:24 AM

To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: ACTIV background slides

David do you have any ACTIV overview slides handy? For a lay audience that is new to the PPP but savvy re COVID

Sent: 6/11/2020 7:20:13 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense], Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2d712dcc6d6a-pollockrc]
Subject: FW: ARDS trial for Covid-19 patients
Attachments: image001.png; ATT00001.bxt; Biomarck BARDA.pptx

Hi Shannon,

Can we please upload this email into DDRMS as FYI for NHLBI, Dr. Gary Gibbons and Dr. Amy Patterson;

-----Original Message-----

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Wednesday, June 10, 2020 10:56 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Cc: Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Subject: FW: ARDS trial for Covid-19 patients

I sent him the survey link.

-----Original Message-----

From: Rajin Ahuja <[REDACTED]> b6
Sent: Tuesday, June 9, 2020 9:35 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: ARDS trial for Covid-19 patients

Dear Mr. Wholley,

Esther Krofah at FasterCures/Milken Institute gave me your name and I am reaching out for assistance with our recent attempt to apply for funding from BARDA. We realize the application portal just abruptly closed and are now looking for where to appropriately submit our grant application related to testing a potential COVID-19 treatment. We hope you might be able to advise where best to focus our effort, perhaps finding support through ACTIV.

I represent Biomarck Pharmaceuticals based in Durham, North Carolina. We have been conducting clinical trials (with previous NIH support) in acute respiratory distress syndrome (ARDS), chronic obstructive pulmonary disease (COPD), and non small cell lung cancer (NSCLC), with a good safety profile in over 300 patients. Our seminal research explains the mode of action of our compound, BIO-11006, which inhibits the pro-inflammatory response of cells involved in the cytokine storm.

In February 2020, Biomarck was completing a phase 2 clinical trial for treating ARDS at four University referral hospitals. In coordination with the DSMB we ended the trial early due to ICUs being overwhelmed with COVID-19 patients. (NCT03202394) Data from this trial met the primary end point and demonstrated a 43% reduction in all cause mortality due to ARDS for ventilated patients. Unfortunately we have no way of knowing if any of those patients had coronavirus, so we would like to conduct further trials to see if BIO-11006 might be an effective treatment when given prior to, or after, patients are put on ventilators because of this virus or related lung injury.

As a small biopharmaceutical company with limited resources, we are excited about positive results in our well-conducted human trials thus far but equally frustrated with navigating a fast changing funding cycle. We need partners to help us gather further evidence about this potential treatment and to get that treatment to patients in need.

We have committed to trying to secure funding for phase 3 clinical trials, have designed ideal clinical trials, and have some study drug available to immediately begin treating patients with coronavirus and with the risk of developing ARDS lung disease. Of course we are inspired to move quickly during this pandemic however, we have been working hard to understand the changing application portals at the NIH, now this week it appears BARDA is not the correct approach.

Can you please advise how ACTIV or other organizations might be able to help position our innovative research to actively study this potentially innovative treatment? We welcome any feedback or assistance for coordination that you may offer. Please don't hesitate to contact me by email or by phone. Thanks very much for your time and I have included the slide presentation from our initial BARDA meeting.

Kind regards,

Rajin Ahuja

APAR0000027924

Rajin Ahuja | Executive Chairman of the Board Biomarck Pharmaceuticals - 2530 Meridian Parkway Suite 300,
Durham, NC 27713
iPhone: + [REDACTED] | [REDACTED] | biomarck.com

Sent: 6/23/2020 2:13:30 AM
To: Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2bf13-walsher]
Subject: RE: Potential ACTIV Partnership

Hi Beth,

I think FNIH should address BeiGene's interest in joining ACTIV – they usually handle the companies joining as partners and I've alerted David Wholley but waiting for his response.

Have they submitted their candidates into the OD portal? If not, I can find out if the Tx clinical working group would prefer they complete the more detailed compound survey vs. using the OD portal.

They can submit the therapeutic candidates into the OD portal and once ACTIV has reviewed they will follow up with the

From: COVID19 Reporting <COVID19Reporting@od.nih.gov>
Sent: Monday, June 22, 2020 8:20 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Potential ACTIV Partnership
Importance: High

And, we're on a roll. I'm not sure how you handle these types of inquiries. Guidance would be appreciated!

From: Bryce Davies <[REDACTED]> **b6**
Date: Sunday, June 21, 2020 at 1:07 AM
To: COVID19 Reporting <[REDACTED]> **b6** "Gorman, Greta (FNIH) [T]" <[REDACTED]> **b6**
Subject: Potential ACTIV Partnership

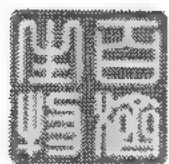
Dear NIH and FNIH team,

My name is Bryce Davies, I am a Senior Director with BeiGene, a biopharmaceutical company that has developed products in the oncology and heme-oncology space. We currently have two potential COVID-19 treatment candidates that we are wanting to bring to the global fight against the pandemic. I understand that there is a portal for submission of ideas and therapeutic candidates, but we would like to explore the possibility of becoming an industry partner with the ACTIV program. BeiGene has extensive experience in the development of new treatments and the operational, regulatory and scientific considerations involved. I strongly believe that, in addition to our potential treatments, we could provide valuable support and insight to this critically important initiative.

I am more than happy to set up a call with our clinical development team to review our two candidates and provide further information on BeiGene.

Regards

Bryce Davies
Senior Director, Clinical Operations
BeiGene Aus Pty. Ltd.
Mobile: [REDACTED] **b6**
Email: [REDACTED] **b6**
Website: www.beigene.com



BeiGene

Sent: 9/17/2020 2:45:44 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Error on the Preclinical WG Page: Tony Punturieri's name

Hi Lauren,

Thanks for the quick response. I'm not certain that Isis and Sheri have given us permission to list their names.

From: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, September 17, 2020 10:36 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Error on the Preclinical WG Page: Tony Punturieri's name

Hi Ashley,

I looked on what I think is the most recent version of the ACTIV roster and did not see Isis Kanevsky and Sheri Hild. Maybe you can double check your file? If not on yours either, maybe Cheryl can confirm if needed (I can email her if needed).

I didn't catch Tony's name listed wrong. I can do another closer double check later today.

From: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, September 17, 2020 10:29 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**; Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Error on the Preclinical WG Page: Tony Punturieri's name

Hi Ashley and Lauren:

Just wanted to double check with the two of you before we made the suggested changes below. Are these okay to make?

Thanks,
Renate

From: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, September 17, 2020 10:15 AM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Error on the Preclinical WG Page: Tony Punturieri's name

Hi Renate,

We were discussing the NIH website today and my Deloitte colleague identified some modifications that should probably be added to the preclinical working group webpage.

Please see the notes below, and let me know if there are any questions.

Best,
Joe

From: Alvarez, Rosa Maria <[REDACTED]>
Sent: Thursday, September 17, 2020 9:39 AM
To: Menetski, Joseph (FNIH) [T] <[REDACTED]>
Cc: Hawk, Harrison <[REDACTED]>
Subject: Error on the Preclinical WG Page: Tony Puntunen's name

Hi Joe,

I noticed Tony's name shows up as below

Antonella (Tony) Punturieri, M.D., Ph.D.
Program Director
Division of Lung Diseases
National Heart, Lung, and Blood Institute, NIH

It should be "Antonella". Probably the order of the degrees should be re-arranged too. Agreed, the normal for is MD PhD

Also, Isis Kanevsky and Sheri Hild are missing from the list

Isis Kanevsky, PhD
Director
Pfizer

- Sheri Hild, PhD
Program Director for the National Primate Research Centers (NPRCs)
Office of Research Infrastructure Programs, NIH

Best,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: [REDACTED]
[REDACTED]

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v.E.1

Sent: 10/21/2020 11:03:18 PM
To: Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2fbf13-walsher]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal
Attachments: Draft revised language for NIH COVID-19 portal 9-22-2020 docx

Hi Beth and Tara,

Apologies for the delay. To provide a quick update to option 2, with many thanks to Renate, OCPL is in the process of adding two buttons on the ACTIV webpage, one for therapeutics that links to the ACTIV portal and a second for vaccines and other candidates that will link to the NIH portal. A similar change will be made on the NIH COVID page to ensure the public clearly knows where to click for therapeutics vs. other submissions.

We took the first crack at providing recommended changes to the current NIH portal language attached and we are simultaneously vetting changes to the ACTIV portal to ensure there's no confusion about what compounds should be submitted to each portal. I will share the revised ACTIV portal language once this is cleared by ACTIV and NCATS.

Please let me know if you have any questions.

Thanks,
Ashley

From: Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, September 18, 2020 11:13 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Sounds good. Happy Friday!

From: "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Friday, September 18, 2020 at 11:11 AM
To: "Walsh, Elizabeth (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Got it – we will work with OCPL on this and circle back with you and Tara. I think we can continue to made progress via email – thanks!

Ashley

From: Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, September 18, 2020 9:59 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**

Cc: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Ashley,

There isn't an OD COVID-19 Portal page. The portal can only be accessed by clicking on a link such as is on the ACTIV or RADx pages. I think the only other place it is listed in a general way is on the main COVID-19 page, but you'd have to check with OCPL on that. Once the language for the links has been established, you can ask them to update any other pages where the portal link appears. I'm free on Monday between 11:30 and 1:30 if there's a time in there that works for you to meet, if needed.

Beth

From: "Parker, Ashley (NIH/OD) [E]" [REDACTED] b6
Date: Friday, September 18, 2020 at 9:26 AM
To: "Walsh, Elizabeth (NIH/OD) [E]" [REDACTED] b6
Cc: "Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> b6
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Beth,

If Monday is better for you we can schedule a time to discuss then or we can continue to handle over email.

We will make the changes on our end for the ACTIV website to ensure we implement two buttons, one for preclinical and clinical therapeutics (linking to the ACTIV portal) and a separate button for vaccines and others (linking to the NIH portal) however it's important to ensure similar changes are made on the NIH portal page hence my note to you and Tara for option 2.

Lauren and I are working on editing language for the ACTIV section of the NIH page and we will send those recommendations today. Given these changes with two links there should be no need for ACTIV submissions to come through the NIH portal but now go directly to ACTIV. I am happy to raise to the ACTIV WG leads to add a contact email to the ACTIV/RedCap link. Currently, companies contact FNIH directly if they have questions.

Thanks,
Ashley

From: Walsh, Elizabeth (NIH/OD) [E] [REDACTED] b6
Sent: Friday, September 18, 2020 9:02 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6; Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Ashley,

I'll have to play it by ear today as I have some larger items that are due today that still need work. Happy to have a call on Monday if needed. My suggestion would be to have one button that says "Submit Your Therapeutic Candidates Here" and one button that says "Submit Your Vaccine Candidate or Other Ideas Here" on the ACTIV homepage as well as anywhere else there is a Redcap survey link. For stuff relevant to ACTIV that still comes in through the OD portal, I can continue to shunt that through the already established channel.

I think it would also be prudent to put a contact email address on the Redcap survey, since a human won't be sending out the link any longer. If people have questions or issues, right now there's nowhere for them to go.

Best,

Beth

From: "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Friday, September 18, 2020 at 8:03 AM
To: "Walsh, Elizabeth (NIH/OD) [E]" <[REDACTED]> **b6** >, "Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Looping in Lauren in case she has time to join us? Lauren is helping us manage updates to the ACT V website.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, September 18, 2020 7:57 AM
To: Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> **b6**
Subject: re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Beth,

Please let me know if you have time today for a call. I'm available between 11-1pm or after 2:30pm.

Thanks,
Ashley

Begin forwarded message:

From: "Schwetz, Tara (NIH/OD) [E]" <[REDACTED]> **b6**
Date: September 18, 2020 at 12:21:33 AM EDT
To: "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6** > "Walsh, Elizabeth (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Ashley,

Apologies for the delayed response – this email must have gotten shunted to my draft folder during one of my (regular) Outlook crashes because I just found it there!

This is really unfortunate to hear, as I think there could/should have been better coordination and communication on this (especially since you weren't even aware it was live!). That said, since it's already live, I suppose the best option is option 2. Regardless, there will still be confusion about what to submit where and you all will still get items that you would automatically rule out and/or that will be irrelevant.

Regarding ExecSec, the process is that they refer people to the portal (recall that it's a way to ease email traffic as well), so it seems a bit circular to refer people to ExecSec, who would in turn refer them to the portal. Obviously, we can change the process; however, I'm not sure ExecSec has the capacity or know edge to make these determinations. Plus, we have the infrastructure of the review group.

Would you please work with Beth to determine how best to structure this and what terminology/language to use to do so? Thanks for keeping us in the loop.

Best,

Tara A. Schwetz, PhD

Associate Deputy Director, NIH

A: Building 1, Room 138

P: **b6** | M: **b6**



From: "Parker, Ashley (NIH/OD) [E]" **b6**
Date: Tuesday, September 15, 2020 at 4:28 PM
To: "Walsh, Elizabeth (NIH/OD) [E]" < **b6** Tara Schwetz
< **b6** >
Cc: "Brodd, Lauren (NIH/OD) [E]" **b6**
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Tara and Beth,

I have new news. Lauren Brodd and I are working closely with OCPL to review and provide updates to the ACTIV website and we noticed the link to the ACTIV portal is publicly available as of 9/10. The ACTIV working group pages were posted at the end of last week and this update included the link to the ACTIV clinical and preclinical portal/RedCap survey approved by FNIH. The ACTIV portal currently lives on the [Preclinical WG page](#) and [Clinical Tx WG page](#).

Apologies for not noticing this sooner! (hence my original question to the war room) – this question was in the draft but was later approved and found today during our weekly review.

Tara – if you agree, I will follow up with the war room tomorrow morning to let them know the ACTIV portal is live and we are working with your team to ensure the submission processes are clearly defined and synched?

Below are a few options for consideration knowing we would need to consult OCPL for any changes to the ACTIV website once we have a clear path forward. These are only ideas but defer to your team if there are other recommendations.

- **Option 1: Do nothing and continue the triage process for ACTIV via OD and then send to FNIH to send the ACTIV/RedCap survey**
 - **Pros:**
 - Current process in place for companies interested in submitting compounds to ACTIV without completing the longer ACTIV/RedCap survey.
 - **Cons:**
 - Now two portals for preclinical and clinical therapeutic submissions which could be confusing to users
 - Selected companies routed to ACTIV currently submit information twice (NIH portal and ACTIV/RedCap) although the ACTIV/RedCap survey takes longer.

- Interested companies go through several channels before receiving email with ACTIV/RedCap link that is now available on the ACTIV website.
 - **Option 2: Ask OCPL to add the ACTIV/RedCap link to the main ACTIV webpage “submit your ideas” (for companies who want to submit preclinical or clinical therapeutic compounds) and keep the existing link to NIH portal (for companies who want to submit vaccines, other). Make any necessary edits to the current ACTIV language provided on the NIH portal.**
 - **Pros:**
 - Interested companies can submit preclinical and clinical therapeutics directly to ACTIV without going through the NIH portal and triage process to receive the link,
 - Any submissions to the NIH portal that should go to ACTIV can be directed to complete the ACTIV/RedCap link on the website.
 - Should limit the number of therapeutic submissions to the NIH portal – limit the number for review and triage.
 - Any follow up questions regarding submissions to ACTIV/RedCap can be directed to FNIH agent prioritization leads for response.
 - **Cons:**
 - Links to 2 different portals could be confusing to users if not clearly defined.
 - Providing link to NIH portal (diagnostics, technologies, vaccines, others) on the ACTIV webpage could be confusing given there is no agent prioritization role for ACTIV beyond therapeutics.
 - **Option 3: Ask OCPL to remove the existing NIH portal link from the ACTIV website and replace with ACTIV/RedCap link. Make any necessary edits to the current ACTIV language provided on the NIH portal.**
 - **Pros:**
 - One link available for ACTIV submissions may avoid confusion.
 - Interested companies can submit preclinical and clinical therapeutics directly to ACTIV agent information without going through the NIH portal and triage process to receive the link.
 - Any submissions to the NIH portal that should go to ACTIV can be directed to complete the ACTIV/RedCap link on the website.
 - Should limit the number of therapeutic submissions to the NIH portal – limit the number for review and triage.
 - Vaccines, diagnostics, others continue to come to the NIH portal via one location NIH COVID page.
 - **Cons:**
 - ACTIV/RedCap may potentially receive compounds beyond therapeutics (vaccines, diagnostics, others) not relevant for ACTIV

Beth – for the irrelevant content coming through the NIH portal, would it be useful to have all general submissions routed directly to ES and only have the serious inquiries for diagnostics, vaccines, technologies reviewed by the cross-NIH team? It may require having a click system for general inquiries, vaccines, diagnostics that leads to a series of targeted questions to weed out the irrelevant submissions although I understand this creates more work! Sighs! ☹️ The current platform could be too easy and potentially invites those types of general submissions which is fine but seems more appropriate for ES to sort – just a thought.

Thanks,
Ashley

From: Walsh, Elizabeth (NIH/OD) [E] b6
Sent: Tuesday, September 15, 2020 6:23 AM
To: Schwetz, Tara (NIH/OD) [E] b6 . Parker, Ashley (NIH/OD) [E] b6
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Tara and Ashley,

For context, 593 of 724 submissions to date have been labeled as preclinical, therapeutic, or "other". I've passed submissions from each of these categories on to ACTIV in the past. Of the 593 submissions, about 20% were approved for dissemination by the review group, and still fewer were appropriate for ACTIV, somewhere between 10% and 15%.

Once the portal was public for a few weeks, we started to receive and have continued to receive a lot of irrelevant content (e.g., anecdotal stories, Fauci/Collins fan mail, and questions that need to be redirected to other channels). These types of responses are the bulk of what is received through the portal now, and it can take a significant amount of time for someone to go through them.

Best,
Beth

From: "Schwetz, Tara (NIH/OD) [E]" b6
Date: Monday, September 14, 2020 at 11:31 PM
To: "Parker, Ashley (NIH/OD) [E]" b6
Cc: "Walsh, Elizabeth (NIH/OD) [E]" b6
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

The clarity is definitely a big piece to consider. Additionally, we are still receiving quite a number of submissions that we would not have any interest in moving forward with (low quality/scientific rigor). What I don't know is how many of these are tx vs. vx, dx, or other. My guess is the tx submissions are a good chunk of these. Looping in Beth to confirm though.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6



From: "Parker, Ashley (NIH/OD) [E]" b6
Date: Monday, September 14, 2020 at 11:24 PM
To: Tara Schwetz <b6>
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

To my understanding, the goal for making the ACTIV portal/RedCap survey public is to allow companies direct access to submit detailed information about "therapeutic" compounds. This information is needed for the ACTIV prioritization process.

The ACTIV portal is specifically for preclinical and clinical therapeutics but nothing else. Vaccines, diagnostics, and other general submissions are not appropriate.

I agree — having two portals is already somewhat confusing and companies who are vetted through the NIH portal may feel confused after receiving a follow-up email to complete the ACTIV survey for a therapeutic compound they've already submitted. If ACTIV wants to move forward with making the link public maybe we'll need a "click here to submit a preclinical or clinical therapeutic agent to ACTIV/FNIH" with link to RedCap on the ACTIV website and NIH portal page but would need a "click here for vaccines, diagnostics, other technologies to link to the NIH portal and edit ACTIV language?" Renate will likely have better ideas!

I have no preference here but agree the process should be streamlined and easy for a submitter to understand. It's also tough to manage the changing landscape —ACTIV initially accepted vaccine candidates but now defer to NIAID now that the Vaccines WG ceased operations as of July 31st and currently meet on an ad hoc basis.

Please let me know if you need any additional info.

Thanks,
Ashley

On Sep 14, 2020, at 9:55 PM, Schwetz, Tara (NIH/OD) [E] b6 wrote:

OK, thanks. What is the goal of making the ACTIV portal public? Are the WGs wanting to invite broad submission? We'll have to discuss how best to link and communicate this, as I do worry this could get confusing to people.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

<image001.png>

From: "Parker, Ashley (NIH/OD) [E]" b6
Date: Monday, September 14, 2020 at 6:19 PM
To: Tara Schwetz b6
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi Tara,

For background, there have been discussions about whether or not the ACTIV portal developed by the ACTIV preclinical and clinical WGs and NCATS should be made public on the ACTIV website. This is independent of the NIH portal and submissions process although we can discuss options for streamlining if ACTIV decides to make it public.

I didn't think we needed to discuss any efforts to streamline/sync the efforts beyond the ongoing process before knowing if ACTIV would like to make this available or continue to send as "invite only." I planned to touch base with you and Beth after knowing what decision ACTIV decides to move forward with but please let me know if you have any questions.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, September 14, 2020 12:37 PM
To: Tabak, Lawrence (NIH/OD) [E] b6 ; Collins, Francis (NIH/OD) [E] < b6 . Wholley, David (FNIH) [T] b6 ; Freire, Maria (FNIH) [T] b6 ; Austin, Christopher (NIH/NCATS) [E] < b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 >; Schwetz, Tara (NIH/OD) [E] b6 >
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Also, the NIH portal (not specific to ACTIV but includes RADx, others) was put in place several months before the ACTIV portal was developed. They are only synched with the NIH portal submissions vetted for ACTIV receiving a link to complete the ACTIV survey.

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, September 14, 2020 12:33 PM
To: Tabak, Lawrence (NIH/OD) [E] b6 >; Collins, Francis (NIH/OD) [E] b6 Wholley, David (FNIH) [T] b6 ; Freire, Maria (FNIH) [T] b6 >; Austin, Christopher (NIH/NCATS) [E] b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 >; Schwetz, Tara (NIH/OD) [E] b6
Subject: RE: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Not related. The information submitted to the ACTIV portal is used for the WGs to prioritize compounds and contains detailed information. The NIH portal has very limited information about the compounds, not sufficient for the agent prioritization process.

No issues with proprietary information as submitters must provide consent.

Hopefully this is helpful context.

Thanks,
Ashley

From: Tabak, Lawrence (NIH/OD) [E] b6 >
Sent: Monday, September 14, 2020 12:28 PM

To: Parker, Ashley (NIH/OD) [E] b6 : Collins, Francis (NIH/OD) [E]
b6 ; Wholley, David (FNIH) [T] b6 : Freire, Maria
(FNIH) [T] b6 ; Austin, Christopher (NIH/NCATS) [E]
b6
Cc: Gadbois, Ellen (NIH/OD) [E] < b6 Schwetz, Tara (NIH/OD) [E]
b6
Subject: Re: ACTIV COVID-19 Clinical and Preclinical Compound Portal

How does this relate to the NIH portal? I thought they were synched up. Are there still proprietary concerns? (cc'ing Tara who has dealt with that issue for NIH portal).

From: "Parker, Ashley (NIH/OD) [E]" b6
Date: Monday, September 14, 2020 at 12:21 PM
To: Francis Collins b6 , "Tabak, Lawrence (NIH/OD) [E]"
b6 , "Wholley, David (FNIH) [T]" < b6
"Freire, Maria (FNIH) [T]" < b6 "Austin, Christopher (NIH/NCATS)
[E]" b6
Cc: "Gadbois, Ellen (NIH/OD) [E]" b6 >
Subject: ACTIV COVID-19 Clinical and Preclinical Compound Portal

Hi All,

If we have time on Wednesday, could we discuss if ACTIV would like to make the ACTIV COVID-19 Clinical and Preclinical Compound Portal also known as the RedCap survey public? The link to the ACTIV portal is currently shared via email to submitters who are vetted through the NIH COVID-19 Candidate and Technologies Portal and when companies send emails to Francis, Janet, FNIH, etc. to inquire about submitting their compound(s) for ACTIV.

This question was raised a while ago and was recently brought to my attention for follow-up.

Thanks,
Ashley

From: Wooldridge, Shannon (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=385B0C281F104789873E956DC91B7C06-BURDENSE]
Sent: 5/4/2020 7:40:56 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Covid-19 Vaccine Project Concept

Never mind – I missed the original email. Sorry!

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, May 4, 2020 3:40 PM
To: Wooldridge, Shannon (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Covid-19 Vaccine Project Concept

Cheryl did not include an attachment but I can ask.

From: Wooldridge, Shannon (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, May 4, 2020 3:38 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Covid-19 Vaccine Project Concept

Did you mean to include an attachment?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, May 4, 2020 3:31 PM
To: Wooldridge, Shannon (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Covid-19 Vaccine Project Concept

From: Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**
Sent: Monday, May 4, 2020 2:02 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Covid-19 Vaccine Project Concept

Hi Ashley

This gentleman has been calling me the last couple days trying to send his concept for the ACTIV project. He asked that when you receive it you could confirm receipt. It wasn't coming through to my FNIH email so I had him send it to my personal email. I'm not sure why it doesn't go through.

Thank you

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[REDACTED] **b6**

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNH's Pandemic Response Fund to combat COVID-19. fnih.org/pandemic



----- Forwarded Message -----

From: Howard Jeffrey Bender <

b6

To: "

b6

b6

Sent: Monday, May 4, 2020, 01:22:55 PM EDT

Subject: Covid-19 Vaccine Project Concept

Hello, Cheryl -

Thanks for your help this morning. Here's my project concept.

Using available NIH databases, my independent research has found three one-in-a-million nucleotide links between the coronavirus and the human genome, forming the D-loop of tRNA. For the past year my work has been followed by your colleague, Kristofor Langlais <b6>, who suggested I continue with lab research needed to confirm my results and speculations. My work is generally described in a YouTube for folks interested in this topic, titled Coronavirus - Using Your DNA Against You. It includes fundamental descriptions but is only about 11 minutes long.

It seems that most vaccine research is focused on finding the right immune cell proteins to keep the coronavirus from infecting human cells in the first place. I'm approaching it differently, with the speculation that at least one of those related nucleotide sequences is part of the reason Covid-19 can become so virulent. As described in the YouTube, if zapping those sequences causes Covid-19 to be a relatively mild infection, perhaps our immune system will form antibodies against it and, by extension, the deadly virus. BTW, I've found different tRNA sequences in both SARS and MERS.

I'm not looking for personal funding, but am asking for a lab researcher to test my concepts and whatever funds are necessary to do it. I suggest four levels, mentioned in the YouTube, with the project stopped for a failure at any level. Those levels are:

1. Using CRISPR or another nucleotide editing system, zap those three sequences in the virus. Whole genome nucleotide sequencing must be done to ensure those sequences have been removed.
2. Using cloned animals, infect one group with the original coronavirus and the other group with the zapped coronavirus. If the zapped animals remain much healthier than the control group, this test will be considered successful.
3. After the healthier animals have fully recovered, infect them with the original coronavirus. If they remain relatively healthy, their immune systems have developed the necessary antibodies, possibly a vaccine from the coronavirus, and this test will be considered successful.
4. Now testing can be done with human subjects, with the hope that humans will also form the necessary antibodies as a self-vaccine, with the researcher watching for any dangerous side effects and other diseases the coronavirus can still create.

If you think my ideas may have merit and can point me to an experimenter to do those tests, we may all defeat this deadly virus.

APAR0000027973

Thanks for any help you can offer.

Cheers,

Howard

Howard Jeffrey Bender, Ph.D.

Sent: 6/11/2020 7:41:18 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: RE: OWS slides for 5 PM -- confidential

Yes, this is all vaccines and nothing on therapeutics.

Slide 7 vaccines programmatic updates: Fill-finish

- Network of sites identified for fill/finish
- Evaluating additional capacity for other candidates – would the clinical capacity WG be any help here if ACTIV partners provided willingness to provide manufacturing capacity in the capacity and capabilities survey?

From: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>
Sent: Thursday, June 11, 2020 3:34 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> Anderson, James (NIH/OD) [E] <[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: Re: OWS slides for 5 PM -- confidential

Presentation is on vaccines; despite a title slide saying diagnostics. I do not see any issues to flag.

(N.B. – VERY CLOSE HOLD; There are some new, evolving discussions between Tony and Moncef on the best operational strategy for the vaccine clinical trials. My guess is Tony will discuss this with Francis.

Cliff

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED]>
Date: Thursday, June 11, 2020 at 3:26 PM
To: "Wholley, David (FNIH) [T]" <[REDACTED]> "Freire, Maria (FNIH) [T]" <[REDACTED]> Lawrence Tabak <[REDACTED]> "Austin, Christopher (NIH/NCATS) [E]" <[REDACTED]> "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED]> "Anderson, James (NIH/OD) [E]" <[REDACTED]> "Parker, Ashley (NIH/OD) [E]" <[REDACTED]>
Subject: OWS slides for 5 PM -- confidential

These have just arrived. I'm in the middle of the ACD meeting and can't really look at details. Can you please go over and flag any concerns for me? I'd need to see your comments by 4:40 PM to be useful.

Thanks, Francis

Sent: 6/23/2020 1:52:48 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: Potential ACTIV Partnership

Hi David,

Please see below – Beigene is interested in becoming a partner with ACTIV. While we can certainly address their interest to submit 2 candidates for review – should we direct them your way regarding joining ACTIV?

Thanks,
Ashley

From: COVID19 Reporting <COVID19Reporting@od.nih.gov>
Sent: Monday, June 22, 2020 8:20 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Potential ACTIV Partnership
Importance: High

And, we're on a roll. I'm not sure how you handle these types of inquiries. Guidance would be appreciated!

From: Bryce Davies <[REDACTED]> **b6**
Date: Sunday, June 21, 2020 at 1:07 AM
To: COVID19 Reporting <COVID19Reporting@od.nih.gov>, "Gorman, Greta (FNIH) [T]" <[REDACTED]> **b6**
Subject: Potential ACTIV Partnership

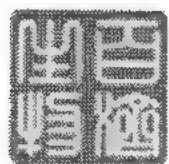
Dear NIH and FNIH team,

My name is Bryce Davies, I am a Senior Director with BeiGene, a biopharmaceutical company that has developed products in the oncology and heme-oncology space. We currently have two potential COVID-19 treatment candidates that we are wanting to bring to the global fight against the pandemic. I understand that there is a portal for submission of ideas and therapeutic candidates, but we would like to explore the possibility of becoming an industry partner with the ACTIV program. BeiGene has extensive experience in the development of new treatments and the operational, regulatory and scientific considerations involved. I strongly believe that, in addition to our potential treatments, we could provide valuable support and insight to this critically important initiative.

I am more than happy to set up a call with our clinical development team to review our two candidates and provide further information on BeiGene.

Regards

Bryce Davies
Senior Director, Clinical Operations
BeiGene Aus Pty. Ltd.
Mobile: [REDACTED] **b6**
Email: [REDACTED] **b6**
Website: www.beigene.com



BeiGene

Sent: 5/14/2020 12:40:38 AM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Rebecca,

Sorry for the delay – I needed to go offline to prepare food and had been online for over 10 hours. I agree we need to be consistent with how we name the groups – I've seen both versions but would go with Preclinical Therapeutics, Clinical Therapeutics, Clinical Trials Capacity, and Vaccines

From: Kolberg, Rebecca (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 13, 2020 7:27 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hi there Dr. Parker!

Can you please take special care to make sure that all the info on the Figure is accurate? It has changed considerably from the last version that I saw and I'm uncertain whether we (NIH, FNIH) made the changes or if they were made by the JAMA graphics department. Also, have the names of the first two working groups changed to Therapeutics Preclinical and Therapeutics Clinical. We need to make sure their names are the same in the text and the figure. Thanks!
Rebecca

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 13, 2020 5:48 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**; Kolberg, Rebecca (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**; Burklow, John (NIH/OD) [E] <[REDACTED]> **b6**; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen <[REDACTED]> **b6**
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Howard Bauchner <[REDACTED]> **b6**; Karen Bucher <[REDACTED]> **b6**
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure here, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

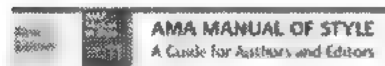
Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA

Managing Editor, *JAMA*

Chair, *AMA Manual of Style*



Sent: 4/28/2020 9:22:52 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: CIHR, FNIH ACTIV and COVID-19
Attachments: WH ACTIV 042920 Updated FINAL.pptx

Sure – please let me know when this will take place. FYI – Francis has the revised version – our visual team sent the slide directly to him – see attached.

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Tuesday, April 28, 2020 5:15 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**
Subject: FW: CIHR, FNIH ACTIV and COVID-19
Importance: High

So I am going to arrange a call. Would you like to be on it?

From: Ryan Perry <[REDACTED]> **b6**
Sent: Thursday, April 23, 2020 4:05 PM
To: Goff, David (NIH/NHLBI) [E] <[REDACTED]> **b6**
Cc: [REDACTED] **b6**, Brian Rowe <[REDACTED]> **b6**, Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: Re: CIHR, FNIH ACTIV and COVID-19
Importance: High

Hi David G.,

Thanks for the connection.

David W. as indicated, there was funding announced today in Canada that look to share similar goals to that of ACTIV. As we have been in regular communication with our colleagues at NHLBI, we are exploring ways to potentially leverage or align activities, and wanted to reach out to see if you have been in contact with any of our colleagues at CIHR and if not, how we can help make the appropriate linkages to support sharing of information. Look forward to hearing from you.

Kind Regards,
Ryan

Ryan Perry, PhD
Associate Scientific Director / Directeur scientifique associé
Institute of Circulatory and Respiratory Health / Institut de la santé circulatoire et respiratoire
Canadian Institutes of Health Research / Instituts de recherche en santé du Canada
E: [REDACTED] **b6**
P: [REDACTED] **b6**
Suite 602, College Plaza
Rue 8215 112 Street NW
Edmonton, AB, Canada, T6G 2C8

On Apr 23, 2020, at 12:24 PM, Goff, David (NIH/NHLBI) [E] <[REDACTED]> wrote:

Ryan and Brian,

The key contact at FNIH for the ACTIV initiative is David Wholley, copied here.

David,

Brian and Ryan are leaders at CIHR in the Institute of Circulatory and Respiratory Health. We are having a series of discussions regarding COVID-19 to learn about activities so we can potentially leverage or align. Today, Brian told me that CIHR has announced an effort that sounds similar in its overall goals to ACTIV. I suggested that additional discussions, that may already be ongoing, might be helpful to fully leverage our joint investments. Please let me know if I can help in any way.

Best regards,

David

David Goff, MD, PhD
Director, Division of Cardiovascular Sciences
National Heart, Lung, and Blood Institute
6705 Rockledge Drive | Suite 309-R
Bethesda, MD 20892

[REDACTED]
b6

t: @NHLBI_HEARTDir

Doing human subjects research? New policies will affect you! [Learn more.](#)

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Sent: 6/13/2020 5:15:50 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]
Subject: BARDA Corona Watch | Therapeutic Candidates for Consideration
Attachments: BARDA CoronaWatch Meeting Notes 20200515 pdf; 20200430 OHSL Presentation pdf

Hi all,

Attached is a list of compounds and a presentation for a FXI mAb shared by one of NIAID's program officers, Steve Smiley who is a reviewer/participant assigned to the **therapeutics Tech Watch (now CoronaWatch) meetings** at BARDA. Steve indicated they have ~10 meetings per week and there are other NIAID experts who join these. He suggested NIH reps who attend the BARDA meetings could assist with sharing compounds with ACTIV – recent focus has been on therapeutic products for infected outpatients for the DAIDS ACTG network but he indicated many products are better suited to phase 2 testing in hospitalized patients.

Steve also suggested we develop a short script for the NIH POCs who attend the BARDA Corona Watch meetings and use this as an opportunity to inform companies about ACTIV. We could link them to our vetting process (i.e. new portal) and/or feed them directly to the working groups. It seems prior to ACTIV, NIAID has used these Corona watch meetings to look for opportunities that would be useful for NIAID networks – Cliff likely has more insight here. The opportunity to expand and be inclusive of ACTIV seems like the right path and an opportunity to stay connected with what comes through BARDA.

Would this be something of interest to the group?

Thanks,
Ashley

Sent: 5/5/2020 3:14:54 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Need help on a JAMA article on ACTIV
Attachments: ACTIV Leadership Slide.pptx

Also, I noticed we updated to leadership slide and a few minor changes were not captured in the revised set.

- We are using the BARDA logo for Disbrow and Johnson considering we all fall under HHS
- Two members listed for VA per FC

Please see attached.

Best,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, May 5, 2020 8:32 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: RE: Need help on a JAMA article on ACTIV

Thanks!

From: Wholley, David (FNIH) [T] [REDACTED] b6
Sent: Tuesday, May 5, 2020 8:31 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: FW: Need help on a JAMA article on ACTIV

Here you go.

Sent: 7/13/2020 9:43:08 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]
Subject: RE: ACTIV Trial Recruitment - Community Engagement

Hi David,

Attached is a slide summarizing the CT enrollment discussions and next steps/immediate actions.

Best,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, July 13, 2020 3:28 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Gonzalez, Nina <[REDACTED]> b6; Elsaid, Olivia <[REDACTED]> b6
Subject: RE: ACTIV Trial Recruitment - Community Engagement

Hi David,

Not a problem – I will send something by COE.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [REDACTED] b6
Sent: Monday, July 13, 2020 2:50 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Cc: Gonzalez, Nina [REDACTED] b6; Elsaid, Olivia [REDACTED] b6
Subject: ACTIV Trial Recruitment - Community Engagement

Hi Ashley,

We have put a slide into the ACTIV EC deck for Wednesday's call with the above title as a placeholder, because I think Francis will want to give the group an update on what has happened in this area since it was discussed on the Leadership Team call July 1. I know that this morning Francis mentioned the conversations with OWS, with the Moderna leadership, and with NIH Leadership, resulting in the formation of some kind of plan that Gary Gibbons and someone whose name I did not catch are responsible for putting together, and which we will subsequently review with the ACTIV 1-4 Study Teams. But I don't have any of the details about what was done, who met with whom, etc, and what the plan is that Francis wants to articulate. I was wondering if you could briefly outline this on a simple strawman slide that we can refine into something more finished to show Francis tomorrow at 1:45 when we do our pre-call. If you can provide 5 or so bullets, our Deloitte colleagues can do whatever is needed to format it into an appropriate slide. Would this be possible? Thanks

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

[REDACTED] b6

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNHI earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Sent: 7/20/2020 4:41:42 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Hever Call 24th July
Attachments: ACTIV slides Hever COVID Meeting July 24, 2020.pptx

Done! Friendly reminder to forward to Hal

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 20, 2020 12:24 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: Hever Call 24th July

Looks good, fine to send (minus slide 9).

Tx, FC

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 20, 2020 12:07 PM
To: Collins, Francis (NIH/OD) [E] <collinsf@exchange.labs.nih.gov> **b6**
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: Hever Call 24th July

Hi Francis,

Please see the attached PDF articles for pre-reads and the draft slides.

There are valid concerns for not sharing the nAbs readiness slide (back pocket slide 9) – Stacey indicated many of the companies being evaluated are at HEVER and some are not yet aware of their status. Slide 5 with the timeline and the colored boxes should be fine.

Once you clear, I will remove the back pocket slide and send materials to Jill and Morten.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, July 20, 2020 7:25 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: Hever Call 24th July

Got it — will do.

Thanks,
Ashley

On Jul 20, 2020, at 5:22 AM, Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6** wrote:

Hi Ashley,

For pre-reads, let's submit the CHIM paper and the Moderna phase 1 paper, both from NEJM.

For the ppts to be presented at the Hever meeting, I'd like to cull some visuals from last week's ACTIV ExComm meeting, but what I have is a pdf – so I'll need some help from you to capture these in the right format. Here's the order: 45, 2, 18, 21, 22, 28, 40. I need you to check with Stacey on slides 21 and 22, to see whether there is confidential information there that should not be shown to Hever. For slide 2 (the roster), please insert a better version that includes the entire Leadership – maybe an update from the July 1 meeting?

Please send me the version you can assemble from these materials so I can have a quick look before it goes to Jill.

Then I'll send it to Hal Barron with a note to give him a heads up about what I intend to cover.

Thanks, FC

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, July 15, 2020 12:13 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Hever Call 24th July

Hi Francis,

Jill and Morten looped me into the Hever request to have your pre-reads submitted by Monday, 7/20. For pre-reads – would you like to share the CHIMs NEJM pub and give an update on the 4 CTs to launch soon which includes mAbs along with substantive updates to the other WGs?

The draft agenda has you and Hal Barron giving a 15 min update on ACTIV/mAb trials (7.5 mins each or will someone take the lead?). Attached are slides we submitted for the June 2nd Hever call, please let me know if you need assistance with pulling draft slides for your presentation. I assume you and Hal will work out the coordination if this hasn't happened already.

FYI – Janet is on the agenda following ACTIV to give an update on OWS non-funded trials – maybe a good idea to coordinate or at least share what you're planning to cover before submitting to Hever?

Thanks,
Ashley

From: Jill Payne <[REDACTED]> **b6**
Sent: Wednesday, July 15, 2020 10:00 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Hever Call 24th July

Ashley

Morten Sogaard has asked me to copy you into this, as you were so helpful with pre-reads last time. Pre-reads are required by the 20th July in time for circulation.

Many thanks

Kind regards

Jill Payne
On behalf of Hever

Email: [REDACTED] b6
Cell: [REDACTED] b6

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From: Jill Payne [mailto:[REDACTED]] b6
Sent: 15 July 2020 11:56
To: [REDACTED] b6
Cc: 'Wood, Gretchen (NIH/OD) [E]'; [REDACTED] b6
Subject: Hever Call 24th July

Dear Dr Collins

Trevor Jones asked me to follow up with you regarding his email last week (see below)

Francis

Please find attached the draft Agenda for our telecon in 14 days time

Please will you confirm that you lead on the ACTIV mAb item

Also please can you arrange for someone to send a pre-read update on ACTIV to Jill for distribution before the event

Many thanks

Trevor

Is this OK with you?

Kind regards

Jill Payne
On behalf of Hever

Email: [REDACTED] b6
Cell: [REDACTED] b6

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This email has been scanned by iomartcloud.
<http://www.iomartcloud.com>

<7.15 ACTIV Executive Committee Meeting 20200714 vFinal.pdf>

Sent: 8/4/2020 3:53:46 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: excel sheets for ACTIV rosters

Hi Lauren,

Thanks for pulling this together – I will send to Cheryl to include future updates on this spreadsheet but we will still need you to assist with cross checking her additions.

I spoke with Cheryl about the KSQ/Rhythm issue and she will let us know.

Also regarding the web content, Emma cc'd you as well on the website updates. Please let me know if you see anything that needs to be flagged. The plan is for OCPL to further develop the Tx and vaccines pages using the information we provided and include the other 2 WGs. We can provide updates as needed although OCPL is taking the lead on the content from here –we'll just need to cross check posted materials. Sound like a plan?

See additional responses in blue below.

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, August 4, 2020 9:32 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: excel sheets for ACTIV rosters

Hi Ashley,

Attached is an updated list, with the organization tabs combined, and updated info for David Meeker.

I think you said there was a separate email chain about David Meeker that I wasn't on, so we just need to clarify if Rhythm Therapeutics is now going to be a leadership organization and/or if KSQ will still be a leadership organization and have a different representative for the leadership meetings. Is that something I should ask Cheryl, or will you be checking with her/someone else? I don't know for sure about that.

In Cheryl's spreadsheet, she has tabs for "industry and private (as defined on the page and is not meant to be used of private)" and "Industry, FDA, BARDA, NIH Group (this is the new leadership group as with BARDA and FDA under government)." I don't have those in our spreadsheet. Are those necessary? No. If so, I would need to create/cross check with hers before this goes to Cheryl. Also, she has her WG in separate tabs, but in our file they are combined into one tab....do you have a preference? Better to have this consolidated in one tab.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, August 3, 2020 3:33 PM

To: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: excel sheets for ACTIV rosters

Thanks! I will send to Cheryl to update from here once we have the additional edits.

I will look out for your email later today or tomorrow.

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, August 3, 2020 3:07 PM
To: Parker, Ashley (NIH/OD) [E] **b6**
Subject: FW: excel sheets for ACTIV rosters

Most updated attached

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health

b6



National Institutes of Health
Turning Discovery Into Health

OSP Blog: [Under the Poliscopes](#)
Twitter: @CWolinetzNIH

From: Brodd, Lauren (NIH/OD) [E]
Sent: Monday, July 27, 2020 11:04 AM
To: Parker, Ashley (NIH/OD) [E] **b6**
Subject: RE: excel sheets for ACTIV rosters

Hi Ashley,

Attached is an updated version of our spreadsheet based on your responses and Cheryl's replies. She has her organized differently, so I don't think this needs to replace hers, but when we receive updates from her then I can add it to this version as we.l.

Thanks,

Lauren

From: Brodd, Lauren (NIH/OD) [E]
Sent: Friday, July 24, 2020 12:57 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: excel sheets for ACTIV rosters

Thanks. I'll email Cheryl (and CC you) on the items that need clarification from her.

APAR0000028034

From: Parker, Ashley (NIH/OD) [E] b6 >
Sent: Friday, July 24, 2020 12:37 PM
To: Brodd, Lauren (NIH/OD) [E] <a b6
Subject: RE: excel sheets for ACTIV rosters

Thanks Lauren, please see comments in purple below.

AP

From: Brodd, Lauren (NIH/OD) [E] b6
Sent: Friday, July 24, 2020 12:09 PM
To: Parker, Ashley (NIH/OD) [E] < b6
Subject: excel sheets for ACTIV rosters

Hi Ashley,

Sorry in advance for this lengthy/complicated email!

I compared Cheryl's "Master and WG Email List for ACTIV" to the excel file that I had put together based on the leadership slides/ACTIV website/Cheryl's WG excel file (both Cheryl's master file and my file are attached).

I found several differences. In Cheryl's "Master and WG Email List for ACTIV" file:

- **Master Email List tab**

- The following **are in my excel file, but not in Cheryl's master tab** (note that some of these might be in her WG tabs, but not in master tab): everyone should be in the master tab – this is probably an oversight and this exact exercise should remedy the situation.

- b6 (leadership)
- b6 (leadership- but note Cheryl had said he was only on one call representing AZ for Mene Pangalos- we had added him to our list but should he be deleted from ours?) we can ask FNIH/Cheryl if he should be included in future emails.
- b6 (leadership)
- b6 (preclinical WG)
- b6 (therapeutics clinical WG)
- b6 (therapeutics clinical WG)
- b6 (therapeutics clinical WG)
- b6 (vaccines WG)
- b6 (we added her to our leadership list)
- b6 (we added her to our leadership list)

- The following **are in Cheryl's master tab but not my excel file**

- Deloitte b6
they should be listed on the WG emails as support – all Deloitte emails are project management help for FNIH.
- b6 (note: he was on earlier leadership slides but not most recent so we deleted him- should he be re-added to ours or deleted from hers?) He probably was unable to attend hence name not on the slides. Only those who can attend will be listed on the slides for that particular meeting. Double check with Cheryl to see if he should remain on the list and if he will also be presenting Gilead.
- b6 looks as if she should be added to the vaccine WG?, not sure why she's not our list.

- [b6] Let's find out where this person belongs on the WGs, clinical TX? and add to the master.
- [b6] vaccine WG?, should be added
- [b6] I do not know who this is – let's ask Cheryl where they belong or if they should be removed
- **Vaccines WG tab:** the following **are in Cheryl's master file WG tab but not in my WG tab/website/her WG file**
 - [b6] prob should be added to the website under vaccines WG – confirm with Cheryl
 - [b6] prob should be added to the website under vaccines WG – confirm with Cheryl
 - [b6] I'm on all the WG's
 - [b6] he's the FNIH vaccines WG lead, he should be on the list
 - [b6] Vaccine WG support Deloitte support staff
- **Clinical Capacity WG tab:** the following **are in Cheryl's master file WG tab but not in my WG tab/website/her WG file** Deloitte and FNIH staff are PM support
 - [b6] Janet is listed on the EC, Cheryl can confirm if she's also on the CC WG
 - [b6] Assume a fairly new member to the vaccines, CC, and PC WGs we can confirm add to the website
 - [b6] I would be listed on all WGs
 - [b6] Deloitte and FNIH staff are PM support
 - [b6] Deloitte and FNIH staff are PM support. Karen is the CC WG lead for FNIH
 - [b6] Deloitte are PM support
- **Preclinical Tx WG tab:** the following **are in Cheryl's master file WG tab but not my WG tab/website/her WG file**
 - [b6] Assume a fairly new member to the vaccines, CC, and PC WGs we can confirm add to the website
 - [b6] I would be listed on all WGs
 - [b6] Joe is the FNIH lead for the PC WG and he's listed on the website
 - [b6] Deloitte are PM support
- **Clinical Trial Tx WG tab:**
 - The following **are in Cheryl's master file WG tab but not my WG tab/website/her WG file** See previous comments
 - [b6]
 - [b6]
 - [b6]
 - [b6]
 - [b6]
 - [b6]
 - The following **are in my WG tab/website/her WG file but not Cheryl's master file WG tab**
 - [b6] not including Jeremy on the master tab was probably an oversight
 - [b6] not including Sylvia on the master tab was probably an oversight -- she should be on the master as well

I hope that makes sense. I'm not sure exactly what she uses each tab for, and if we need to resolve some/all of the differences or should just keep separate files. I have not gone through her industry/private tab or the Industry/FDA/BARDA/NIH tab as I figured there were enough differences in the other tabs that we could figure out how we want to proceed first. Not urgent, but happy to answer questions or discuss further if needed.

Thanks,

Lauren

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health



National Institutes of Health
Turning Discovery Into Health

OSP Blog: [Under the Poliscopes](#)

Twitter: @CWolinetzNIH

Sent: 7/13/2020 6:41:14 PM
To: Espinoza, Tasha (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c590ff12ed4d4cc087e2d4ab3f91a437-espinozata]
CC: Mazzucco, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0a2582111be424db9016255e7aa3c44-mazzuccoa]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Operation Warp Speed Update for Tomorrow (7/14)
Attachments: Copy of Integrated_Operation Warp Speed Global Budget Template - Therapeutics May24.xlsx

Hi Tasha,

Attached is the budget request we submitted for ACTIV therapeutic trials.

From: Mazzucco, Anna (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 13, 2020 1:03 PM
To: Espinoza, Tasha (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: Re: Operation Warp Speed Update for Tomorrow (7/14)

Ah ok, that's helpful context and sounds different from the program management support I am familiar with through Tara's office. Perhaps Ashley can help fill in some additional details- looping in also David Wholley at FNIH who can provide details on timing.

Very Sincerely,

Anna

From: "Espinoza, Tasha (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Monday, July 13, 2020 at 12:56 PM
To: "Mazzucco, Anna (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: Operation Warp Speed Update for Tomorrow (7/14)

Hi Anna,

Thanks so much for your help. My contact on the OWS team told me this was related to ACTIV monoclonal antibodies activity for NIH/OD. They mentioned that they were working with an estimate of \$2.5M. A lot of what these meetings I've been attending are to help coordinate the budget estimates and timing of when the funding is needed, so that's the type of information I am looking for. This information is helpful to the OWS team so they can ensure that the funding gets to the agencies when it's needed for obligation.

Thanks!
Tasha

From: Mazzucco, Anna (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 13, 2020 11:12 AM
To: Gladman, Jordan (NIH/OD) [E] <[REDACTED]> **b6**; Espinoza, Tasha (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: Operation Warp Speed Update for Tomorrow (7/14)

Sure- happy to help try to clarify/track this down.

OD funds are being used to support program management for the cross-cutting trans-NIH COVID-19 related projects, including ACTIV and FNIH's involvement there. I am looping in Pat because she may have more specifics on the exact request if helpful!

Very Sincerely,

Anna

From: "Gladman, Jordan (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Monday, July 13, 2020 at 11:07 AM
To: "Espinoza, Tasha (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Mazzucco, Anna (NIH/OD) [E]" <[REDACTED]> **b6** "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: Operation Warp Speed Update for Tomorrow (7/14)

Tasha,

I suspect Anna Mazzucco and/or Ashly Parker (cc'ed) would be the people most likely to know about FNIH Program Management Support. Anna has been working with Tara with the Program Management side of ACTIV/COVID efforts and Ashley is the superstar helping NIH and FNIH coordinate ACTIV. Do either of you have any insight into the request? Anna and Ashley Tasha is now the point person working to coordinate the OWS and NIH COVID budget process so leadership can understand where our money is allocated and going.

Best,

Jordan

From: Espinoza, Tasha (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 13, 2020 10:58 AM
To: Gladman, Jordan (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Operation Warp Speed Update for Tomorrow (7/14)

Good morning!

Hope you had a great weekend.

In prepping for the OWS Therapeutics meeting tomorrow, I wanted to reach out to see if you knew anything about an OD request for Program Management for FNIH. It came up at a meeting last week and would like to track down more information. I reached out to the Budget Officer and there has been funding already obligated, but it sounds like this is a new request.

Thanks,
Tasha

Tasha Espinoza
National Institutes of Health, Office of Budget
Building 1, Room B1-18A
[REDACTED] **b6**

Sent: 5/13/2020 10:25:31 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Tolman, Brett [b6 George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020
Attachments: activ vaccine subcomm tte clinical endpoints discussion slides for distribution final.pptx

Thanks, Mike -- I will share what you've provided and also send Dr. Collins slide 11.

Thanks again!
Ashley

-----Original Message-----

From: Santos, Michael (FNIH) [T] < b6
Sent: Wednesday, May 13, 2020 6:20 PM
To: Parker, Ashley (NIH/OD) [E] < b6
Cc: Tolman, Brett < b6 George, Jill (NIH/OD) [E] < b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley,

well, their slides came in just in time for me to send you back this one. Of course feel free to use whatever makes sense!

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] < b6
Sent: Wednesday, May 13, 2020 5:59 PM
To: Santos, Michael (FNIH) [T] < b6
Cc: Tolman, Brett < b6 George, Jill (NIH/OD) [E] < b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Greatly appreciate it -- thanks, Mike!

Ashley

-----Original Message-----

From: Santos, Michael (FNIH) [T] < b6
Sent: Wednesday, May 13, 2020 5:58 PM
To: Parker, Ashley (NIH/OD) [E] < b6
Cc: Tolman, Brett < b6 George, Jill (NIH/OD) [E] < b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley,

Thanks for the opportunity to review. The plan has changed a bit since that slide was made, so I will made edits to it now and get it back to you within about 15 min.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] < b6
Sent: Wednesday, May 13, 2020 5:55 PM
To: Santos, Michael (FNIH) [T] < b6
Cc: Tolman, Brett < b6 George, Jill (NIH/OD) [E] < b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Mike,

Unfortunately, Larry has not shared the slides so I've pulled from other slides to draft something quickly to send to Dr. Collins. He is asking for the results from today's WG meeting can you please confirm or edit/add information where needed?

Thanks,
Ashley

-----Original Message-----

From: Santos, Michael (FNIH) [T] <[REDACTED]> b6
Sent: Wednesday, May 13, 2020 2:49 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Cc: Tolman, Brett <[REDACTED]> b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley,

Yes, of course please feel free to reach out to Larry and Peter directly as well. If you could cc us, that would be great.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, May 13, 2020 2:48 PM
To: Santos, Michael (FNIH) [T] <[REDACTED]> b6
Cc: Tolman, Brett <[REDACTED]> b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Mike,

Thank you for the details below and I understand you are still waiting for the slides. I may need to contact Larry Corey directly to ask for the slides presented today given the time sensitive timeframe.

Thanks so much,
Ashley

-----Original Message-----

From: Santos, Michael (FNIH) [T] <[REDACTED]> b6
Sent: Wednesday, May 13, 2020 2:30 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Cc: Tolman, Brett <[REDACTED]> b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley,

Yes, as you heard we don't have the slides yet from Larry and Peter (we asked for them in advance but they were still finishing them). Once we get them we will share them with you.

I think the report to Francis is that there will be a harmonized protocol that is expected to have agreement on primary endpoints and sampling/lab plans, among other parameters. NIAID presented a draft plan today, but deciding on those parameters will take more discussion among the group and, crucially, input from the FDA (which Marion Gruber offered a channel for).

The operational question of a shared DSMB was discussed, including suggestions for an uber-DMC that aggregates from study DMCs. The exact implementation of the concept will be worked out.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, May 13, 2020 2:09 PM
To: Santos, Michael (FNIH) [T] <[REDACTED]> b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Mike,

I've noted you are waiting for Larry or Peter to share the slides. Also, it seems the working group would like to further review the harmonized protocol proposal and discuss again before making final decisions about the shared DSMB ect. Is this right?

Thanks!
Ashley

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 1:40 PM
To: Santos, Michael (FNIH) [T] <[REDACTED]> b6
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Hi Mike,

Do we have a copy of the vaccine slides that describe the vaccine harmonized protocol being presented now? If so, can you please share so I can edit? Dr. Collins presents to the ICD group tomorrow and would like to include -- see his note below.

Is this possible?

Thanks,
Ashley

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, May 13, 2020 1:28 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6; Anderson, James (NIH/OD) [E]
<[REDACTED]> b6
Cc: Tabak, Lawrence (NIH/OD) [E] <lawrence.[REDACTED]> b6; Wholley, David (FNIH) [T] <[REDACTED]> b6
George, Jill (NIH/OD) [E] b6
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Looks good, though I have done some trimming and re-arranging.

I want to add a slide to summarize what the Vaccines WG came up with today on the harmonized master protocol -- will there be a shared DSMB, shared agreement on endpoints, lab assays, etc. Can that be provided by the end of the day?

FC

Sent: 7/23/2020 10:24:43 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: RE: ACTIV graphics 1.0
Attachments: DRAFT ACTIV Checkerboard 072320.pptx

Hi Joe and Karen,

Please see the attached draft grid of ACTIV/NIH trials with the attached spreadsheet. Included in tab 3 are additional types of trial information that can be gathered – I do not necessarily recommend sharing the spreadsheet with the war room but using for our purposes.

Edit as you see fit and please let me know if you'd like to make edits. It may be a good idea for me to send to FC tonight for review, prior to sharing broadly with the war room group tomorrow morning.

I standby for any edits – after dinner of course!

Thanks,
Ashley

From: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, July 23, 2020 8:52 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV graphics 1.0

Thank you Ashley. Karen, terrific progress.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, July 23, 2020 8:51 AM
To: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: ACTIV graphics 1.0

I will jump off of the Vaccines WG meeting to talk then.

Thanks,
Ashley

From: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, July 23, 2020 8:49 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: ACTIV graphics 1.0

Ashley, would 2-2:30 work for you?

From: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, July 23, 2020 8:48 AM

To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Tountas, Karen (FNIH) [T] **b6**
Subject: RE: ACTIV graphics 1.0

I am busy up to about 12:30... Sorry. Any time after 2?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, July 23, 2020 8:35 AM
To: Menetski, Joseph (FNIH) [T] **b6** Tountas, Karen (FNIH) [T] **b6** >
Subject: RE: ACTIV graphics 1.0

I'm available now or 30 mins and then free again at 10am.

Thanks,
Ashley

From: Menetski, Joseph (FNIH) [T] **b6**
Sent: Thursday, July 23, 2020 8:32 AM
To: Parker, Ashley (NIH/OD) [E] **b6** Tountas, Karen (FNIH) [T] **b6**
Subject: RE: ACTIV graphics 1.0

Lots of great comments.

The goal was to compare therapies, with populations, so I think this y axis on the dot plot is good, but could be separated more, I think.

Can we have another short call? I think there are some things that I am missing. I am not sure the phase of the trial is something that needs to be prominent, more important is the type of therapeutic and the end date.

This may need to be a series of graphs and then they can pick from them??

Joe

From: Parker, Ashley (NIH/OD) [E] **b6**
Sent: Wednesday, July 22, 2020 7:57 PM
To: Tountas, Karen (FNIH) [T] **b6** ; Menetski, Joseph (FNIH) [T] **b6**
Subject: RE: ACTIV graphics 1.0

Hi Karen,

This looks like a great start! A few minor comments/thoughts and responses to your questions

- Should we keep all drug therapies separate? i.e. place antivirals in a bucket of its own? We would see a salmon colored dot twice. Maybe also include a bucket for other therapies which will be blank for the moment and include various vaccine treatment options (mRNA, protein, etc.)?
- I think the current model clearly indicates which compounds are being tested in the various population groups -- if this was the original request or intent, Joe can confirm based on conversations with Maria and the war room. Current graphic doesn't make it clear to know which phase(s) the trials are in although I see the reference target on the bottom right. We discussed the option of showing the trial phases on the x-axis with the patient populations on the y-axis, and compounds on the z-axis but I do not have a preference here.
- Should we add additional population groups: emergency department, hospitalized ventilated vs. hospitalized non-ventilated, mild/moderate/severe disease? Only a thought, do we want to track recovery and include recovered patients eventually in a separate graphic?
- Should all of the dots be the same size (the salmon dot looks smaller but maybe it's my vision!)

- ACTIV-2 they are starting with their phase 2 study. Subjects will be outpatient - is that outpatient asymptomatic or symptomatic or both? I would assume outpatient symptomatic but Stacey can confirm.
- ACTIV-4 they have three protocols. I think we should track each separately. Your thoughts? Agree we should track them separately and they will launch/start enrollment at different times.
 - Need list of agents to be tested. I am happy to ask NHLBI contacts for this information unless we prefer to start with Stacey?
 - Need IND status. In-hospital was approved by the DSMB last week. Prenatal will be reviewed by the DSMB today 7/22. I do not know the IND status of the post-hospitalization - Stacey will likely have information.
- Need target enrollment numbers for each - I just stuck in numbers for illustrative purposes (see above). I have not seen the target enrollment numbers for ACTIV-4, should we ask Stacey? I am happy to ask NHLBI for ACTIV-4 if needed.
- Need anticipated launch dates for each trial. I've only seen launch weeks: ACTIV-2-4 week of July 27 (ACTIV-4 inpatient week of July 27, outpatient and post-hosp. is unclear to me) and ACTIV-1- mid August.
- Enrollment tracker looks good to me! No comments at the moment.

Please let me know if we should start with Stacey for the remaining responses or if you prefer I contact NHLBI.

Thanks,
Ashley

From: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, July 22, 2020 5:27 PM
To: Menetski, Joseph (FNIH) [T] <[REDACTED]>; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: ACTIV graphics 1.0

Hi Joe and Ashley,

I have been thinking about graphic representation for the ACTIV CT details and still like what we had talked about this morning, but excel does not allow creation of x,y,z scatter plots (or at least I cannot figure it out), so...

I made two plots:

- one for information about each trial (I'm a little iffy on this plot, it needs something...),
- and the other to track the status of enrollment versus the target (all numbers are just for demo - I don't have the real enrollment targets and obviously no subjects have enrolled yet.).

See what you think.

Of note, excel would not let me change the axis labels so these are just text boxes - not sure what was going on but...



Some of the information in the attached spreadsheet needs a bit more granularity as detailed below – do e then of you have the answers?

- ACTIV-2 – they are starting with their phase 2 study. Subjects will be outpatient – is that outpatient asymptomatic or symptomatic or both?
- ACTIV-4 – they have three protocols. I think we should track each separately. Your thoughts?
 - Need list of agents to be tested
 - Need IND status
- Need target enrollment numbers for each – I just stuck in numbers for illustrative purposes (see above)
- Need anticipated launch dates for each trial

Best,

Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



Confidentiality Notice

APAR0000028061

Sent: 4/28/2020 8:54:34 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: DoD Representatives
Attachments: WH ACTIV 042920 Updated (004) Plus DOD and Gen. Talley.pptx

Oh My -- I've added Brig. Gen. Talley his government agency logo and a logo for DOD -- can't fit.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Tuesday, April 28, 2020 4:31 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6>; Wholley, David (FNIH) [T] <[REDACTED] b6>
Subject: FW: DoD Representatives

Can we quickly add Brigadier General Talley and DoD to the ACTIV roster slide? I'd like to be able to show we're connected -- BG Talley will be in the room tomorrow at the WH.

FC

-----Original Message-----

From: Lane, Cliff (NIH/NIAID) [E] <[REDACTED] b6>
Sent: Tuesday, April 28, 2020 4:26 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6>; Wholley, David (FNIH) [T] <[REDACTED] b6>; Freire, Maria (FNIH) [T] <[REDACTED] b6>
Subject: DoD Representatives

BG Talley concurs with the following nominees to support the ACTIV initiative:

Executive Group: BG Talley (Dr. Dertzbaugh backup),
[REDACTED] b6

Preclinical: Dr. Louise Pitt, USAMRIID, [REDACTED] b6

Clinical: CAPT Tim Burgess, USUHS, [REDACTED] b6

Vaccines: Dr. Nelson Michael, WRAIR, [REDACTED] b6

Sent: 8/4/2020 12:42:23 PM
To: Kilgore, Nicole R CIV USARMY (USA) [b6]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]
Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

Hi Nicole,

1:30pm was the only time available for Dr. Collins' schedule today. Will you be able to make this work?

I am cc'ing Ayanna McManus who handles Dr. Collins' schedule.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: b6

-----Original Message-----

From: Kilgore, Nicole R CIV USARMY (USA) <b6>
Sent: Tuesday, August 4, 2020 8:36 AM
To: Kurilla, Michael (NIH/NCATS) [E] b6 >
Cc: Parker, Ashley (NIH/OD) [E] <b6> Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA) <b6>
<b6> Collins, Francis (NIH/OD) [E] <b6> Schmitt, Clare (NIH/NCATS) [E] b6 >; Atkinson, Jane (NIH/NCATS) [E] <b6>
Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Good morning Ashley,

Our availability today is as follows.

12-1 and 3:30-5:00.

Thanks,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- b6
Cell- b6
Fax- b6
email b6

-----Original Message-----

From: Kurilla, Michael (NIH/NCATS) [E] [mailto:michael.b6]
Sent: Monday, August 3, 2020 6:50 PM
To: Kilgore, Nicole R CIV USARMY (USA) <b6>
Cc: Parker, Ashley (NIH/OD) [E] <b6> Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA) <b6>
<b6> Collins, Francis (NIH/OD) [E] <b6> Schmitt, Clare (NIH/NCATS) [E] <b6> Atkinson, Jane (NIH/NCATS) [E] <b6>
Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

Nicole,

Good to reconnect (although I would have preferred under different circumstances). We have had quite a bit of discussion regarding a number of convalescent plasma trials and would like to explore the possibility of harmonizing the Sullivan trial (NCT04373460) with the C3PO trial sponsored by NHLBI/NIH

APAR0000028131

that is quite similar. Both trials could benefit from access to rapid POC diagnostics and several other enhancements.

Would it be possible to schedule a time tomorrow with your and/or other relevant DOD staff to discuss options?

Ashley Parker will handle scheduling.

Michael G Kurilla, MD-PhD
Director, Division of Clinical Innovation National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health
6701 Democracy Blvd, Room 934
Bethesda, MD 20892

b6

b6

I'm not blessed or merciful. I'm just me. I've got a job to do and I do it.

I'm there for the old and young, innocent and guilty, those who die together and those who die alone.
In the end, I'm there for all of them.

-Death, from Neil Gaiman's Sandman #20 Façade

-----Original Message-----

From: Kilgore, Nicole R CIV USARMY (USA) b6
Sent: Sunday, August 2, 2020 10:00 PM
To: Collins, Francis (NIH/OD) [E] < b6
Cc: Parker, Ashley (NIH/OD) [E] < b6 Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA)
b6 >; Kurilla, Michael (NIH/NCATS) [E] < b6
Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Dear Drs Collins and Kurilla,

The ongoing study is being funded under a contract with the DOD-JPEO. I believe there are opportunities for collaboration for accelerating the study. If this is something you would like to pursue, I suggest we discuss further on the best approach to move forward.

Look forward to talking soon.

Regards,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702

Ph- b6
Cell- b6
Fax- b6
email - b6

-----Original Message-----

From: Dan Hanley [mailto: b6
Sent: Sunday, August 2, 2020 7:59 PM
To: b6
Cc: Parker, Ashley (NIH/OD) [E] <ash b6 Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA)
< b6 Kilgore, Nicole R CIV USARMY (USA) b6 David
Sullivan b6 Shmuel Shoham < b6 Karen Lane < b6 Kurilla,
Michael (NIH/NCATS) [E] b6 >; Daniel Ford < b6
Subject: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Dear Dr Collins ,

Attached please find the details behind the request you directed us to provide for the specific needs to accelerate our outpatient trials. We have copied Ashley Parker and Mike Kurilla as requested.

APAR0000028131

As promised on our thursday submission we have added budgetary detail and rational. After discussion with our institutional officer and CTSA PI, Daniel Ford we can put this plan into action with verbal notification of intent to support. Thus we can begin this enhancement of effort immediately with the intent and likelihood of completing the trial on September 30 of this year as requested

Thank you for your interest in our 2 trials.

Dan Hanley

David Sullivan

Shmuel Shoham

From: Peleton <[REDACTED]>
Date: Wednesday, July 29, 2020 at 2:10 PM
To: "Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA)" <[REDACTED]>
Subject: FW: CP RCT Meeting Summary -- and urgent timeline

From: Collins, Francis (NIH/OD) [E] [Caution-mailto: [REDACTED]]
Sent: Wednesday, July 29, 2020 1:54 PM
To: Tabak, Lawrence (NIH/OD) [E] <lawrence.[REDACTED]> Anderson, James (NIH/OD) [E]
<[REDACTED]> Lauer, Michael (NIH/OD) [E] <[REDACTED]> Austin, Christopher
(NIH/NCATS) [E] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> Fauci, Anthony
(NIH/NIAID) [E] <[REDACTED]> Gibbons, Gary (NIH/NHLBI) [E] <[REDACTED]> Patterson,
Amy (NIH/NHLBI) [E] <[REDACTED]> Rutter, Joni (NIH/NCATS) [E] <[REDACTED]> Kurilla,
Michael (NIH/NCATS) [E] <[REDACTED]> Woodcock, Janet (FDA/CDER)
<[REDACTED]> Disbrow, Gary (OS/ASPR/BARDA) <[REDACTED]> Freire, Maria (FNIH)
[T] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Marks, Peter (FDA/CBER)
<[REDACTED]> .gov>; Hoots, W. Keith (NIH/NHLBI) [E] <[REDACTED]> Glynn, Simone
(NIH/NHLBI) [E] <[REDACTED]> Groesch, Mary (NIH/NHLBI) [E] <[REDACTED]> Shipp,
Allan (NIH/NHLBI) [E] <[REDACTED]> Punturieri, Antonello (NIH/NHLBI) [E]
<[REDACTED]> .edu; David Sullivan <[REDACTED]>
Shmuel Shoham <ssh[REDACTED]> Dan Hanley <[REDACTED]> mila. [REDACTED]
<[REDACTED]> Jayaweera, Dushvantha (NIH) <[REDACTED]> .edu>; Ralph Sacco [REDACTED]
<[REDACTED]> Santos, Michael
(FNIH) [T] <msantos@fnih.org>; b. [REDACTED] ; Roberts David
<[REDACTED]> Homer, Marv (OS/ASPR/BARDA) [REDACTED] b6
<[REDACTED]> Arturo Casadevall
<[REDACTED]> Collins, Francis (NIH/OD) [E]
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: CP RCT Meeting Summary -- and urgent timeline

Dear Colleagues,

I greatly appreciate everyone who was available to join the convalescent plasma RCT discussion yesterday on such short notice. As promised, attached is the meeting summary. I am asking the principal investigators from each of the RCTs to send responses to the questions outlined below to Dr. Ashley Parker, <[REDACTED]> Caution-mailto: [REDACTED] > cc'ing me by noon tomorrow, July 30.

Here is what I'm looking for:

* If resources were unlimited, what could be done to accelerate enrollment?

APAR0000028131

- * What barriers would need to be overcome?
- * How many participants could be enrolled by August 31? By September 30?
- * When would a read-out of the study be possible?
- * What would that cost?

Many of you have already provided clinical trial information in the attached excel spreadsheet, many thanks.

Thank you,

Francis

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

Sent: 5/2/2020 1:25:01 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: JAMA
Attachments: JAMA draft outline 043020 100AM.docx

Resending in case this was lost in your inbox.

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, May 1, 2020 1:10 AM
To: Collins, Francis (NIH/OD) [E] < > b6
Subject: RE: JAMA

Hi Francis,

Please see attached outline for JAMA piece. Is this enough to get you started?

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] < > b6
Sent: Thursday, April 30, 2020 8:45 PM
To: Parker, Ashley (NIH/OD) [E] < > b6
Subject: RE: JAMA

Actually let me give you a little more time – I'm not really going to be able to work on this until Saturday morning. So COB Friday would be fine. 😊

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, April 30, 2020 3:45 PM
To: Parker, Ashley (NIH/OD) [E] < > b6
Subject: RE: JAMA

COB would be fine

From: Parker, Ashley (NIH/OD) [E] < > b6
Sent: Thursday, April 30, 2020 3:04 PM
To: Collins, Francis (NIH/OD) [E] < > b6 >
Subject: RE: JAMA

Hi Francis,

Happy to help, how soon do you need this? – on the call with BARDA for the portal training until 4:30pm.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] < > b6 >
Sent: Thursday, April 30, 2020 2:41 PM

To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: JAMA

Hi Ashley,

How about drafting a bulleted outline to get me started?

FC

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, April 30, 2020 2:40 PM
To: Kolberg, Rebecca (NIH/OD) [E] **b6**
Cc: Tabak, Lawrence (NIH/OD) [E] **b6** >; Wholley, David (FNIH) [T] **b6** >; Freire, Maria (FNIH) [T] **b6** >; Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> **b6** Lane, Cliff (NIH/NIAID) [E] **b6** >; Anderson, James (NIH/OD) [E] **b6** Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: JAMA

FYI

From: Howard Bauchner <[REDACTED]> **b6**
Sent: Thursday, April 30, 2020 2:30 PM
To: Collins, Francis (NIH/OD) [E] **b6**
Cc: Phil Fontanarosa **b6**
Subject: JAMA

Francis

Wonderful chatting –

Viewpoint – about 1400-1500 words – 5-7 references; can in addition have a table or figure which may help describe the 4 areas – Therapies; Vaccines, RCTs, Pre-clinical.

Do NOT submit but send directly to Phil and me. We will edit it and return it to you for a revision the same day it is received.

Please avoid the royal “we”; quotes, clichés, words like provider and impact.

Look forward to reading it – and sounds quite exciting – and may indeed need these efforts for some sense of normalcy – whatever that maybe - to resume in the Fall.

Stay healthy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

Sent: 6/24/2020 8:44:49 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]
Subject: FW: OD Portal ACTIV Candidates
Attachments: 2020-06-24_VettedCOVID-19 PortalSubmissions_ACTIV.xlsx

Please see candidates received/vetted June 13-19 – these are all listed as therapeutics.

From: Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, June 24, 2020 4:32 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: OD Portal ACTIV Candidates

Hi Ashley,

See attached for the candidates pertinent to ACTIV this week from the OD Portal. There were 41 submissions, 13 of which were determined to be viable. Seven have been passed on to ACTIV.

Best,
Beth

Elizabeth R. Walsh, PhD
Health Science Policy Analyst
Immediate Office of the Director, NIH
A: Building 1, Room 108
P: [REDACTED] | M: [REDACTED]
--

Sent: 7/13/2020 5:41:10 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: Operation Warp Speed Update for Tomorrow (7/14)
Attachments: Copy of Integrated Operation Warp Speed Global Budget Template - Therapeutics May24.xlsx

Hi Larry,

Please see request below – should I share the attached budget request with Tasha?

From: Mazzucco, Anna (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 13, 2020 1:03 PM
To: Espinoza, Tasha (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: Re: Operation Warp Speed Update for Tomorrow (7/14)

Ah ok, that's helpful context and sounds different from the program management support I am familiar with through Tara's office. Perhaps Ashley can help fill in some additional details- looping in also David Wholley at FNIH who can provide details on timing.

Very Sincerely,

Anna

From: "Espinoza, Tasha (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Monday, July 13, 2020 at 12:56 PM
To: "Mazzucco, Anna (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: Operation Warp Speed Update for Tomorrow (7/14)

Hi Anna,

Thanks so much for your help. My contact on the OWS team told me this was related to ACTIV monoclonal antibodies activity for NIH/OD. They mentioned that they were working with an estimate of \$2.5M. A lot of what these meetings I've been attending are to help coordinate the budget estimates and timing of when the funding is needed, so that's the type of information I am looking for. This information is helpful to the OWS team so they can ensure that the funding gets to the agencies when it's needed for obligation.

Thanks!
Tasha

From: Mazzucco, Anna (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 13, 2020 11:12 AM
To: Gladman, Jordan (NIH/OD) [E] <[REDACTED]> **b6** >; Espinoza, Tasha (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: Operation Warp Speed Update for Tomorrow (7/14)

Sure- happy to help try to clarify/track this down.

OD funds are being used to support program management for the cross-cutting trans-NIH COVID-19 related projects, including ACTIV and FNIH's involvement there. I am looping in Pat because she may have more specifics on the exact request if helpful!

Very Sincerely,

Anna

From: "Gladman, Jordan (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Monday, July 13, 2020 at 11:07 AM
To: "Espinoza, Tasha (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Mazzucco, Anna (NIH/OD) [E]" <[REDACTED]> **b6**, "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: Operation Warp Speed Update for Tomorrow (7/14)

Tasha,

I suspect Anna Mazzucco and/or Ashly Parker (cc'ed) would be the people most likely to know about FNIH Program Management Support. Anna has been working with Tara with the Program Management side of ACTIV/COVID efforts and Ashley is the superstar helping NIH and FNIH coordinate ACTIV. Do either of you have any insight into the request? Anna and Ashley Tasha is now the point person working to coordinate the OWS and NIH COVID budget process so leadership can understand where our money is allocated and going.

Best,

Jordan

From: Espinoza, Tasha (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 13, 2020 10:58 AM
To: Gladman, Jordan (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Operation Warp Speed Update for Tomorrow (7/14)

Good morning!

Hope you had a great weekend.

In prepping for the OWS Therapeutics meeting tomorrow, I wanted to reach out to see if you knew anything about an OD request for Program Management for FNIH. It came up at a meeting last week and would like to track down more information. I reached out to the Budget Officer and there has been funding already obligated, but it sounds like this is a new request.

Thanks,
Tasha

Tasha Espinoza
National Institutes of Health, Office of Budget
Building 1, Room B1-18A
[REDACTED] **b6**

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]
Sent: 5/29/2020 1:04:47 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Hughes, Eric [b6] Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
CC: Earle Melody (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6511f04014a749a78e9243ec427ae7fc-earlem2]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]
Subject: Linking Up NHLBI COVID Plans and ACTIV Plans
Attachments: Linkages NHLBI COVID and ACTIV Plans 060520 SHOW final.pptx; LINKAGE MTG NHLBI COVID-19 CT Tracker_060520.pdf; current status of ACTIV MP discussions with NHLBI; NHLBI_ACTIV Touch Base June 5, 2020.docx
Location: see webex below
Start: 6/5/2020 4:30:00 PM
End: 6/5/2020 5:30:00 PM
Show Time As: Busy

Required Attendees: Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Read, Sarah (NIH/NIAID) [E]; Hughes, Eric; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Kiley, James (NIH/NHLBI) [E]; Hoots, W. Keith (NIH/NHLBI) [E]; Freire, Maria (FNIH) [T]

Optional Attendees: Earle, Melody (NIH/NHLBI) [E]; Hill, Zoe (NIH/NHLBI) [C]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Simon, Dina (NIH/OD) [C]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; Groesch, Mary (NIH/NHLBI) [E]

Materials sent by NHLBI for today's call attached

Join Webex meeting

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/5/2020 3:57:22 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: current status of ACTIV MP discussions with NHLBI

For our call with Gary at 12:30, I thought it would be good to briefly remind ourselves of where we are in our interactions with NHLBI on the existing and planned ACTIV protocols. Below is per Stacey:

- ACTIV-1 (immunomodulators, inpatient)— No major involvement from NHLBI, but we had asked them to lead it and they said no.
- ACTIV-2 (mAbs, outpatient) – Not a lot of involvement yet, but have expressed interest in having the protocol at some of their sites. This will likely need more conversation.
- ACTIV-3 (mAbs, inpatient) – Heavily integrated in the writing team. Two NHLBI networks joining INSIGHT: PETAL and CSTN.
- ACTIV-4 (anticoagulants, inpatient)— NHLBI is fully leading this effort and is updating the TX-Clinical WG each week. Keith Hoots updated this week. As seen in the OWS presentation, there is \$40M budgeted for this trial, but also an additional \$35M for an outpatient study.
- ACTIV-5 (“de novo” protocols for antivirals, other mechanisms not being adequately tested elsewhere—in development)— We haven’t broached this yet.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]
Sent: 4/17/2020 1:46:20 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Subject: Daily ACTIV Call

Attachments: Untitled Attachment

Location: b6 Passcode: b6

Start: 4/20/2020 12:30:00 PM

End: 4/20/2020 1:00:00 PM

Show Time As: Busy

Recurrence: Daily
every day from 8:30 AM to 9:00 AM

Required Attendees: Wholley, David; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Freire, Maria (FNIH) [T]; Parker, Ashley (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Carver, Trea (NIH) [C]

Dial-in: b6

Passcode: b6

Dr. Tabak as Leader: b6

From: Brodd, Lauren (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 6/8/2020 12:42:05 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: FOR YOUR REVIEW: Revised ACTIV Slide Deck with 3 Design Options

Hi Ashley,

I meant to put 3-5pm today, so I could also do sometime between 4-5pm today if that would work. If not, anytime between 2.30-4pm tomorrow works for me so just let me know when you prefer.

Thanks!

Lauren

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, June 8, 2020 8:39 AM
To: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: FOR YOUR REVIEW: Revised ACTIV Slide Deck with 3 Design Options

Hi Lauren,

Happy Monday! Unfortunately, those times do not work for my calendar today. Let's try for some time between 2:30-4:00pm tomorrow?

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, June 8, 2020 7:57 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: FOR YOUR REVIEW: Revised ACTIV Slide Deck with 3 Design Options

Hi Ashley,

Sure that sounds good. I could do sometime between 9:30-10:45am, 11:30-12pm, or 3-4pm. Would any of those times work for you?

Thanks,

Lauren

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health

OSP Blog: [Under the Poliscope](#)

Twitter: @CWolinetzNIH

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Sunday, June 7, 2020 8:14 AM
To: Brodd, Lauren (NIH/OD) [E] [REDACTED]
Subject: RE: FOR YOUR REVIEW: Revised ACTIV Slide Deck with 3 Design Options

Hi Lauren,

Renate cc'd you on the note below. If you're still available to assist, I'm thinking we can discuss a plan on Monday for helping us to keep the information on the website up to date and further discuss plans to provide information for the 4 working group webpages and build on what you've developed.

If this works for you, let's find a time to discuss on Monday.

Thanks!
Ashley

Begin forwarded message:

From: "Myles, Renate (NIH/OD) [E]" [REDACTED]
Date: June 6, 2020 at 4:58:01 PM EDT
To: "Collins, Francis (NIH/OD) [E]" [REDACTED] "Wholley, David (FNIH) [T]" [REDACTED], "Parker, Ashley (NIH/OD) [E]" [REDACTED], "Tabak, Lawrence (NIH/OD) [E]" [REDACTED], "Freire, Maria (FNIH) [T]" [REDACTED], "Wolinetz, Carrie (NIH/OD) [E]" [REDACTED]
Cc: "Burklow, John (NIH/OD) [E]" [REDACTED], "Fine, Amanda (NIH/OD) [E]" [REDACTED], "Wojtowicz, Emma (NIH/OD) [E]" [REDACTED], "Hallett, Adrienne (NIH/OD) [E]" [REDACTED], "Higgins, Lauren (NIH/OD) [E]" [REDACTED], "Gadbois, Ellen (NIH/OD) [E]" [REDACTED], "Brodd, Lauren (NIH/OD) [E]" [REDACTED], "Meltzer, Abbey (FNIH) [T]" [REDACTED], "Gorman, Greta (FNIH) [T]" [REDACTED], "Menetski, Joseph (FNIH) [T]" [REDACTED], "Adam, Stacey (FNIH) [T]" [REDACTED], "Tountas, Karen (FNIH) [T]" [REDACTED], "Santos, Michael (FNIH) [T]" [REDACTED], "James, Stephanie (FNIH) [T]" [REDACTED]
Subject: Re: FOR YOUR REVIEW: Revised ACTIV Slide Deck with 3 Design Options

Terrific! I will get the image on slide 4 changed and share the final deck on Monday with this team and the IC communication directors for IC use. I'll do a regular check in with Ashley to make sure we keep the slides current.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

[REDACTED]

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Saturday, June 6, 2020 3:44:56 PM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>;
Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>;
Freire, Maria (FNIH) [T] <[REDACTED]>; Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED]>; Fine, Amanda (NIH/OD) [E] <[REDACTED]>;
Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]>; Hallett, Adrienne (NIH/OD) [E] <[REDACTED]>;
Higgins, Lauren (NIH/OD) [E] <[REDACTED]>; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>;
Brodd, Lauren (NIH/OD) [E] <[REDACTED]>; Meltzer, Abbey (FNIH) [T] <[REDACTED]>;
Gorman, Greta (FNIH) [T] <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>;
Adam, Stacey (FNIH) [T] <[REDACTED]>; Tountas, Karen (FNIH) [T] <[REDACTED]>;
Santos, Michael (FNIH) [T] <[REDACTED]>; James, Stephanie (FNIH) [T] <[REDACTED]>
Subject: RE: FOR YOUR REVIEW: Revised ACTIV Slide Deck with 3 Design Options

I'm fine with the larger hexagon version, it's no longer looming and ominous. ☺

Just need to propagate the new image for clinical trials to slide 4.

FC

From: Myles, Renate (NIH/OD) [E] <[REDACTED]>
Sent: Friday, June 5, 2020 3:10 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>;
Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>;
Freire, Maria (FNIH) [T] <[REDACTED]>; Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED]>; Fine, Amanda (NIH/OD) [E] <[REDACTED]>;
Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]>; Hallett, Adrienne (NIH/OD) [E] <[REDACTED]>;
Higgins, Lauren (NIH/OD) [E] <[REDACTED]>; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>;
Brodd, Lauren (NIH/OD) [E] <[REDACTED]>; Meltzer, Abbey (FNIH) [T] <[REDACTED]>;
Gorman, Greta (FNIH) [T] <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>;
Adam, Stacey (FNIH) [T] <[REDACTED]>; Tountas, Karen (FNIH) [T] <[REDACTED]>;
Santos, Michael (FNIH) [T] <[REDACTED]>; James, Stephanie (FNIH) [T] <[REDACTED]>
Subject: FOR YOUR REVIEW: Revised ACTIV Slide Deck with 3 Design Options

Hi Francis and team:

I've updated the content for the slides based on the feedback received. To address the "ominous" hexagons (Carrie thought this would be a good band name), we have three new versions for your consideration. Please note though that we retain the hexagon design to maintain a uniform identity with the [ACTIV website](#).

1. Larger hexagon header
2. Smaller hexagon header
3. No header

Let me know which design you prefer and if there are any additional concerns with the content.

Many thanks,

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]
Sent: 8/12/2020 9:12:14 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3ced1fd96-sepulvedade]

Subject: Daily ACTIV Call

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Dial-in: **b6** Passcode: **b6**

Start: 9/11/2020 12:00:00 PM

End: 9/11/2020 12:30:00 PM

Show Time As: Busy

Recurrence: Weekly

Occurs every Friday from 8:00 AM to 8:30 AM effective 9/11/2020 until 11/27/2020.

Required Attendees: Wholley, David, Collins, Francis (NIH/OD) [E], Tabak, Lawrence (NIH/OD) [E], Lane, Cliff (NIH/NIAID) [E], Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C], Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]

Extending to end of November

Dial-in: **b6**

Passcode: **b6**

Dr. Tabak as Leader: **b6**

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Attachments: ACTIV Daily Update 20200911.pptx

Start: 9/11/2020 12:00:00 PM

End: 9/11/2020 12:30:00 PM

Recurrence: (none)

Extending to end of November

Dial-in: | b6

Passcode: b6

Dr. Tabak as Leader: b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/11/2020 11:15:41 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremcc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200911.pptx
Attachments: ACTIV Daily Update 20200911.pptx

Here are slides for this morning's war room, Friday September 11, 2020

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Attachments: ACTIV Daily Update 20201009.pptx

Start: 10/9/2020 12:00:00 PM
End: 10/9/2020 12:30:00 PM

Recurrence: (none)

Required Attendees: Melencio, Cheryl (FNIH) [T]; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]

Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; Freire, Maria (FNIH) [T]

Extending to end of November

Dial-in: b6
Passcode: b6

Dr. Tabak as Leader: b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 10/23/2020 11:06:03 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20201023.pptx
Attachments: ACTIV Daily Update 20201023.pptx

Please see attached the slides for this morning's war room, Friday October 23.

From: Lane, Cliff (NIH/NIAD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D7E368A3137473BBCE161547A82F2DE-CLANE]
Sent: 10/30/2020 12:12:46 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV-3 by date of symptom onset

Subgroup analysis based on days since symptom onset is below – please treat as confidential.

Table 6.6: Subgroup Analyses for the Day 5 Ordinal Pulmonary Outcome

Baseline Subgroup	Group A		Group B		Proportional Odds ^{a)}			Interaction
	No.	Score ^{b)}	No.	Score ^{b)}	OR	95% CI	P-value	P-value
Days since symptom onset^c								
≤ 5	58	2.8	45	2.6	1.02	0.48, 2.19	.96	.70
6-8	45	2.9	52	2.7	0.79	0.37, 1.69	.55	
9 +	59	2.9	53	2.8	1.10	0.55, 2.19	.79	

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 11/6/2020 12:47:42 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20201106vFrev.pptx
Attachments: ACTIV Daily Update 20201106vFrev.pptx

Here are slides for today's war room call, Friday November 6.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 11/13/2020 3:37:29 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20201113.pptx
Attachments: ACTIV Daily Update 20201113.pptx

For tomorrow's war room, Friday November 13

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]
Sent: 9/25/2020 3:34:38 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Alvarez, Rosa Maria [b6]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [b6]; Chen, Helen Q. [b6]; Gonzalez, Nina [b6]; Hawk, Harrison [b6]; Mendelson, Jesse [b6]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [b6]; Tolman, Brett [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [b6]; Sorosa, Alex [b6]; Connelly, Sarah [b6]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]

Subject: ACTIV Leadership Team Pre-call
Attachments: 11.19 ACTIV Leadership Team Meeting 20201117 for review.pptx
Location: see webex below
Start: 11/17/2020 5:00:00 PM
End: 11/17/2020 5:30:00 PM
Show Time As: Busy

Required Attendees: Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Alvarez, Rosa; Anderson, Margaret; Appel, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Sorosa, Alex; Connelly, Sarah
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

2011-05-03 10:00 AM EDT

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/28/2020 12:35:20 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]
Subject: mAbs Summit

Hi Francis

This is a heads up about the upcoming mAbs Summit #2 and the need to work with your calendar to accommodate the meeting.

Stacey, Karen, and I had a very good discussion with Kevin Bugin and Ciaran Lawlor of OWS this morning about running the follow-up summit with the heads of R&D and the clinical leads from the seven companies Janet spoke to on her CEO Summit. **b6** All but Regeneron are likely to attend. Purpose of the call, which is proposed to last two hours, is to assess the companies' readiness and timetable to test their drugs in ACTIV and secure their participation. Topics to discuss protocol synopses, network and CRO engagement, entry criteria, supply and other issues, with substantial send-ahead documentation so we can focus on where there may be issues.

Kevin told us Janet has spoken with you and it is agreed you will lead the call (or, I guess, co-lead it with Janet if that works). Other attendees will include the ACTIV TX-Clinical WG co-chairs (Sarah Read and Eric Hughes), the protocol leads from ACTG (Judy Currier) and INSIGHT (Jim Neaton), and one or two folks from FDA, likely John Farley, who has been sitting in on the ACTIV protocol development discussions, and some reps from BARDA and perhaps DoD. We can add someone from NHLBI depending on how our call with them goes.

We are targeting the call for around Tuesday, June 9, with a pre-call to go over slides, etc with you and Janet on the afternoon of Friday June 5. Cheryl will take care of the scheduling but we will start with your and Janet's calendars of course. FNIH will work with Kevin and Ciaran to assemble the slides and all the materials including an agenda. We will use either Zoom or Webex depending on whether DoD has any platform restrictions. I will update you with more information on this afternoon's war room call.

Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Alvarez, Rosa Maria [b6]
Sent: 8/31/2020 3:11:16 AM
To: Alvarez, Rosa Maria [b6] b6 Hewitt, Judith (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Cat. b6 Gatto,
Gregory [b6] Young, John [b6] Colvis, Christine (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];
Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D
 [b6] b6 Jonson, Samantha (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Hawk, Harrison
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Hild,
Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]
CC: Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen
 [b6]

Subject: ACTIV Preclinical - Data Portal Implementation
Attachments: Canceled: ACTIV Preclinical - Data Portal Implementation; Canceled: ACTIV Preclinical - Data Portal Implementation
Location: https://deloitte.zoom. b6

Start: 5/21/2020 1:00:00 PM
End: 5/21/2020 2:00:00 PM
Show Time As: Busy

Recurrence: (none)

Join Meeting

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To: Hawk, Harrison [b6] Alvarez, Rosa Maria [b6] Young, John
Rodriguez, Robin D [b6] Hewitt, Judith (NIH/NIAD) [E]
[b6] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6]
[b6] Gatto, Gregory [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];
Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];
Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd];
[b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Hild,
Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]
CC: Florence, Clint (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen
[b6]

Subject: Canceled: ACTIV Preclinical - Data Portal Implementation

Start: 9/3/2020 1:00:00 PM

End: 9/3/2020 2:00:00 PM

Show Time As: Free

Recurrence: (none)

Hi all,

We will be canceling this meeting tomorrow. Be on the lookout for an email from Sam with questions we would like to discuss offline.

Best,
Rosa

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To: Alvarez, Rosa Maria [b6] Annaliesa. [b6] [b6] Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6]; Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]

CC: Reynolds, Lindsey [b6] Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc] Mason, Stephen [Stephen. [b6]

Subject: Canceled: ACTIV Preclinical - Data Portal Implementation

Start: 10/8/2020 1:00:00 PM

End: 10/8/2020 2:00:00 PM

Show Time As: Free

Recurrence: (none)

Hi all,

We will be canceling this meeting as we are having the Preclinical WG Meeting during this time. We will discuss updates during the Preclinical WG.

Regards,
Rosa

Microsoft Exchange Information for meeting attendees

Join Meeting

Password:

[b6]

APAR0000019813

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA74284158B86087D08B628E6F-MELENCIOC]
Sent: 8/12/2020 9:05:06 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa74284158b86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3ced1fd96-sepulvedade]
Subject: Daily ACTIV Call
Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: Dial-in: **b6** Passcode: **b6**
Start: 9/9/2020 12:00:00 PM
End: 9/9/2020 12:30:00 PM
Show Time As: Busy
Recurrence: Weekly
every Wednesday from 8:00 AM to 8:30 AM
Required Attendees: Wholley, David; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]

Extending to end of November

Dial-in: **b6**
Passcode: **b6**

Dr. Tabak as Leader: **b6**

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/16/2020 11:09:55 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: 9.15.2020 Needs Assessment Meeting_v1.pdf
Attachments: 9.15.2020 Needs Assessment Meeting_v1.pdf

Here are slides from yesterday's Needs Assessment summary meeting I will not go through this page by page—will instead summarize outcomes and action items—but thought you might appreciate having the slides. David

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/16/2020 10:54:25 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200916 ver2.pptx--Please use this version
Attachments: ACTIV Daily Update 20200916 ver2.pptx

Begging your pardon, I just received a new version of the war room slides for this morning, Wednesday September 16, containing an additional update from the Clinical Trials WG. Please use this version for our discussions today. Thanks, David

To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Attachments. ACTIV Daily Update 20200923.pptx; ACTIV-2 ACTIV-3 Needs Assessment Final Report FINAL 09222020 pptx

Start: 9/23/2020 12:00:00 PM

End: 9/23/2020 12:30:00 PM

Recurrence: (none)

Extending to end of November

Dial-in: [REDACTED] **b6**

Passcode: [REDACTED] **b6**

Dr. Tabak as Leader: [REDACTED] **b6**

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 9/29/2020 9:51:17 AM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: Results from HEVER Survey on pandemic preparedness (post-Covid-19)
Attachments: Tabulated version Hever survey.docx; Notes of Hever Group Meeting Sept 2nd 2020 Final.docx

Can we discuss this at tomorrow's War Room?

Francis

From: Hudson, Thomas J <[REDACTED]> **b6**
Sent: Monday, September 28, 2020 1:45 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6** Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Hudson, Thomas J <[REDACTED]> **b6**
Subject: Results from HEVER Survey on pandemic preparedness (post-Covid-19)

Dear Francis,

You will recall that following the last HEVER call, company representatives were asked to indicate their interest in the two models that were presented to members regarding pandemic preparedness (beyond COVID-19). I presented the "Information and Platform Sharing Consortium" and Andy Plump presented the "Pandemic NewCo". Trevor sent us the replies from companies (see attached). As you can see, 9 companies are interested in the Consortium and 7 in the NewCo. I also received messages from other organizations (Evotec, Gates, etc.).

Trevor asked both Andy and I to reach out to interested parties to further define the options and bring back to the next Hever call planned in early November.

You may remember saying that the Consortium proposal mimics an AMP. I also heard you say that on the ACTIV call last Wednesday that FNIH is thinking of organizing a workshop on pandemic preparedness.


Before I reach out to other companies and other organizations such as CARE/IMI, I would like hear from you how you would like to proceed in regards to coordination. I would not want to catalyze a working group just with company representatives. I also do not want to initiate an effort if this is already underway by credible players such as FNIH. Finally – I think that a pandemic preparedness initiative will work best if it leverages the research structures, processes and capabilities that were launched by ACTIV.

I know that you are very busy. It would be fine for me to initiate discussions with David.

Please advise,

Tom

THOMAS HUDSON
Senior Vice-President, R&D
Chief Scientific Officer


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From: Hudson, Thomas J
Sent: Friday, September 25, 2020 9:52 AM
To: Plump, Andrew <b6> Harriet Keane b6
Cc: Edd Fleming <edd> b6
Subject: FW: [EXTERNAL] Fwd: Results from Hever Survey

Andy, Harriet and Edd,

This is the first of two messages received from Trevor this morning. I will provide comments on the second message.

Tom

THOMAS HUDSON
Senior Vice-President, R&D
Chief Scientific Officer


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From: Prof Trevor M Jones CBE FMedSci <b6>
Sent: Friday, September 25, 2020 2:13 AM
To: Hudson, Thomas J <b6>

APAR0000019826

Cc: [REDACTED] b6 Geoff Frew <[REDACTED]> b6

Subject: [EXTERNAL] Fwd: Results from Hever Survey

Tom

Re your note

Please see this note that I sent to Mikael earlier this week

(I was waiting for his response before sending it to you and to Andy ...and I have sent a reminder)

Hopefully, we can "push the buttons" on the next steps later today

Do you have a view on the "One meeting or two" issue

Best regards

Trevor

----- Original Message -----

From: "Jill Payne" <[REDACTED]> b6

To: "[REDACTED] b6" <[REDACTED] b6> "[REDACTED] b6"

<[REDACTED] b6>

Cc: "Trevor Jones CBE" <[REDACTED] b6> "Geoff Frew" <[REDACTED] b6>

Sent: Wednesday, 23 Sep, 20 At 12:18

Subject: Results from Hever Survey

Dear Mikael

Geoff, Jill and I have now analysed the responses to the recent Polls on

1. Establishing an "Information and Platform Sharing Consortium" (as outlined by Tom Hudson)
2. Establishing a "Pandemic NewCo" (as outlined by Andy Plump)
3. Arranging further Hever Group VOVID-19 meetings

Please find the results attached.

You will see that there is sufficient interest in proposals 1. and 2. to move to the next step of calling the interested parties together for more detailed discussions.

This could be two separate meetings (arranged by Tom and by Andy) or (in view of the desire of some companies to participate in both) one meeting (arranged, say, by Andy)

Although it is disappointing that some of the leading COVID-19/Virology/Vaccine players have not expressed an interest in pursuing either of these initiatives, it might be worth inviting them to participate in the "next step" meeting(s)?

(Obviously, once these Consortia are established it may well be that those companies will reconsider!)

Concerning a further Hever Group COVID-19 meeting, you will see that there is a sufficient interest in a meeting covering Vaccines and Antivirals.

We propose, therefore to arrange a teleconference in early November 2020 ...say, in the first week... and would be grateful if you would let us know your preferred dates/times. (We can agree an Agenda nearer the date)

Your comments on these items would be most welcome

Best regards

Trevor

Kind regards

Jill Payne

On behalf of Hever

Email: [REDACTED] b6

Cell: [REDACTED] b6

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Prof Trevor M Jones CBE FMedSci

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/30/2020 3:31:53 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200930.pptx
Attachments: ACTIV Daily Update 20200930.pptx

Here are the slides for tomorrow morning's meeting, Wednesday, September 30.

To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Attachments. ACTIV Daily Updates 20201014.pptx; RE: ACTIV Daily Updates 20201014.pptx

Start: 10/14/2020 12:00:00 PM

End: 10/14/2020 12:30:00 PM

Recurrence: (none)

Extending to end of November

Dial-in: [REDACTED] **b6**

Passcode: [REDACTED] **b6**

Dr. Tabak as Leader: [REDACTED] **b6**

From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 10/14/2020 11:41:10 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: ACTIV Daily Updates 20201014.pptx
Attachments: NIH SARS-CoV2 Antiviral Therapeutics Summit Draft Agenda.docx

Attached is the draft agenda for the NIH SARS-CoV2 Antiviral Therapeutics Summit being planned for Nov 6. Feedback is welcome; invitations need to go out soon.

Thanks
Jim

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Wednesday, October 14, 2020 7:37 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>
Freire, Maria (FNIH) [T] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]> Anderson, James (NIH/OD) [E] <[REDACTED]>
Subject: ACTIV Daily Updates 20201014.pptx

Slides for this morning's war room, Wednesday October 14.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/4/2020 8:59:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [b6] Adam, Stacey (FNIH) [T] [b6] Alvarez, Rosa [b6] Anderson, Margaret [b6] Gonzalez, Nina [b6] James, Stephanie (FNIH) [T] [b6] Kim, Elizabeth [b6] Menetski, Joseph (FNIH) [T] [b6] Santos, Michael (FNIH) [T] [b6] Stratton, Ben [b6] Tolman, Brett [b6] Tountas, Karen (FNIH) [T] [b6] Wachtel, Jonathan [b6] Wholley, David (FNIH) [T] [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Elsaid, Olivia [b6] Tabak, Lawrence (NIH/OD) [E] [b6]
CC: Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6] Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]
Subject: ACTIV Leadership Call Slide Review
Location: see webex below
Start: 5/4/2020 9:45:00 PM
End: 5/4/2020 10:15:00 PM
Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Elsaid, Olivia; Tabak, Lawrence (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

Join Webex meeting

Meeting number (access code) [b6] Meeting password: [b6]

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[b6] Call-in toll number (US/Canada)

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Join the meeting

If you are a host, go here to view host information. **IMPORTANT NOTICE**

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/28/2020 12:35:20 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]
Subject: mAbs Summit

Hi Francis

This is a heads up about the upcoming mAbs Summit #2 and the need to work with your calendar to accommodate the meeting.

Stacey, Karen, and I had a very good discussion with Kevin Bugin and Ciaran Lawlor of OWS this morning about running the follow-up summit with the heads of R&D and the clinical leads from the seven companies Janet spoke to on her CEO Summit (Lilly/Abcellera, Cell Trion, Roche, GSK/Vir, Amgen, AZ, and Regeneron). All but Regeneron are likely to attend. Purpose of the call, which is proposed to last two hours, is to assess the companies' readiness and timetable to test their drugs in ACTIV and secure their participation. Topics to discuss protocol synopses, network and CRO engagement, entry criteria, supply and other issues, with substantial send-ahead documentation so we can focus on where there may be issues.

Kevin told us Janet has spoken with you and it is agreed you will lead the call (or, I guess, co-lead it with Janet if that works). Other attendees will include the ACTIV TX-Clinical WG co-chairs (Sarah Read and Eric Hughes), the protocol leads from ACTG (Judy Currier) and INSIGHT (Jim Neaton), and one or two folks from FDA, likely John Farley, who has been sitting in on the ACTIV protocol development discussions, and some reps from BARDA and perhaps DoD. We can add someone from NHLBI depending on how our call with them goes.

We are targeting the call for around Tuesday, June 9, with a pre-call to go over slides, etc with you and Janet on the afternoon of Friday June 5. Cheryl will take care of the scheduling but we will start with your and Janet's calendars of course. FNIH will work with Kevin and Ciaran to assemble the slides and all the materials including an agenda. We will use either Zoom or Webex depending on whether DoD has any platform restrictions. I will update you with more information on this afternoon's war room call.

Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]
Sent: 8/12/2020 8:58:42 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3ced1fd96-sepulvedade]
Subject: Daily ACTIV Call
Attachments: Untitled Attachment; Untitled Attachment; Daily ACTIV Call: Ashley is the Leaders today - LAT is out for YK.; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: Dial-in: **b6** Passcode: **b6**
Start: 9/7/2020 12:00:00 PM
End: 9/7/2020 12:30:00 PM
Show Time As: Busy
Recurrence: Weekly
every Monday from 8:00 AM to 8:30 AM
Required Attendees: Wholley, David; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]

Extending to end of November

Dial-in: **b6**
Passcode: **b6**

Dr. Tabak as Leader: **b6**

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugneskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Attachments: 9.11.2020 Needs Assesment Meeting_FINAL.pdf; ACTIV Daily Update 20200914.pptx

Start: 9/14/2020 12:00:00 PM

End: 9/14/2020 12:30:00 PM

Recurrence: (none)

Extending to end of November

Dial-in: | b6

Passcode: b6

Dr. Tabak as Leader: b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/14/2020 11:29:11 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; John H. Freeman ([b6] [b6] Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: 9.11.2020 Needs Assessment Meeting_FINAL.pdf
Attachments: 9.11.2020 Needs Assessment Meeting_FINAL.pdf

Slides from the first Needs Assessment Survey results discussion last Friday, 9/11.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/14/2020 11:20:10 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20200914.pptx
Attachments: ACTIV Daily Update 20200914.pptx

Slides for this morning's war room, Monday September 14.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/21/2020 11:44:46 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: Inclusion exclusion "crosswalk" and master protocol "cheat sheet" documents
Attachments: Copy of ACTIV Endpoint Comparison Across ACTIV Master Protocols 20200915.xlsx; ACTIV Master Protocols ACTIV-CP Comparison Cheat Sheet 20200916.pdf

As promised, these have been reviewed with trial leadership and are near enough final changes to send to you. They will be used by leadership at the sites to sort out which ACTIV trials are appropriate in a given context.

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

b6

fni.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Attachments: ACTIV Daily Update 20201005.pptx

Start: 10/5/2020 12:00:00 PM

End: 10/5/2020 12:30:00 PM

Recurrence: (none)

Extending to end of November

Dial-in: [REDACTED] **b6**

Passcode: [REDACTED] **b6**

Dr. Tabak as Leader: [REDACTED] **b6**

To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

CC: Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]

Attachments: ACTIV Daily Update 20201019.pptx

Start: 10/19/2020 12:00:00 PM

End: 10/19/2020 12:30:00 PM

Recurrence: (none)

Extending to end of November

Dial-in: [REDACTED] **b6**

Passcode: [REDACTED] **b6**

Dr. Tabak as Leader: [REDACTED] **b6**

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 10/26/2020 11:46:59 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20201026.pptx
Attachments: ACTIV Daily Update 20201026.pptx

Slides for this morning's war room call, Monday October 26.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 11/9/2020 2:59:15 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: question re: COVID-19 vaccines given to patients on B-cell depleting agents

Hi all, can we please discuss best answer to b4 email below on tomorrow's war room? Thanks. David

From: Santos, Michael (FNIH) [T] < b6 >
Sent: Friday, November 6, 2020 4:38 PM
To: Wholley, David (FNIH) [T] < b6 >
Subject: RE: question re: COVID-19 vaccines given to patients on B-cell depleting agents

b5

The topic that we want to discuss in our meeting is b5
Schedule-wise, this conversation won't happen until Dec at the earliest.

So my best answer is that we b5

If you want some thing for him faster than that, b5

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Wholley, David (FNIH) [T] b6
Sent: Friday, November 6, 2020 4:24 PM
To: Santos, Michael (FNIH) [T] b6
Subject: FW: question re: COVID-19 vaccines given to patients on B-cell depleting agents

Any idea how I would answer this? Who I would go to? Thanks

From: [REDACTED] b6
Sent: Thursday, November 5, 2020 9:45 AM
To: Wholley, David (FNIH) [T] [REDACTED] b6
Cc: [REDACTED] b6
Subject: question re: COVID-19 vaccines given to patients on B-cell depleting agents

Hi David,

b4

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 11/9/2020 12:39:32 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremcc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcc42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: ACTIV Daily Update 20201109.pptx
Attachments: ACTIV Daily Update 20201109.pptx

Please see attached this morning's war room slides Monday November 9.

From: Jonson, Samantha (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE2F69369D654BEF89B0D39B145D69A7-JONSONSG]
Sent: 6/24/2020 1:35:21 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]
Subject: RE: ACTIV Daily Update 20200624.pptx

Hi Ashley,

The call is being scheduled for 11 today. I will forward you the meeting details once we receive them from the FDA.

You likely have not seen db. Chris emailed Francis and Larry regarding their access to the link on Saturday. Here is the link to the tracker (you will need to be on VPN): [COVID19 Clinical Trial Tracker](#). I did give you, Ellen and Michelle access. Per FDA's request, I've only provided access to a **very limited** list of people (you 3, Francis, Larry, Chris, Mike and 6 other project and informatics support people at NCATS).

Sam

Samantha Jonson, MPS [E]
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Cell: b6
E-mail: b6



National Center
for Advancing
Translational Sciences

COLLABORATE. INNOVATE. ACCELERATE.

From: Austin, Christopher (NIH/NCATS) [E] <b6>
Sent: Wednesday, June 24, 2020 8:46 AM
To: Parker, Ashley (NIH/OD) [E] <b6>
Cc: Jonson, Samantha (NIH/NCATS) [E] <b6>
Subject: RE: ACTIV Daily Update 20200624.pptx

Copying Sam re the call.

And see my note to Michelle this morning about the databases – there should be no confusion.

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, June 24, 2020 8:44 AM
To: Austin, Christopher (NIH/NCATS) [E] b6
Subject: RE: ACTIV Daily Update 20200624.pptx

Is this the 10am call or a different time? I would like to join if possible – too many databases and I'm not certain that I've seen this one.

Thanks!
Ashley

From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Wednesday, June 24, 2020 8:35 AM
To: Wholley, David (FNIH) [T] b6 ; Collins, Francis (NIH/OD) [E] b6 >; Tabak, Lawrence (NIH/OD) [E] b6 , Freire, Maria (FNIH) [T] b6 , Lane, Cliff (NIH/NIAID) [E] b6 ; Parker, Ashley (NIH/OD) [E] b6 ; Anderson, James (NIH/OD) [E] b6
Subject: RE: ACTIV Daily Update 20200624.pptx

Just got confirmation that the "Kevin" on the call today with NCATS staff to discuss ACTIV access to the CT tracker is indeed Kevin Bugin. I'll let you know outcome.

From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, June 24, 2020 7:23 AM
To: Collins, Francis (NIH/OD) [E] b6 ; Tabak, Lawrence (NIH/OD) [E] b6
Austin, Christopher (NIH/NCATS) [E] b6 >, Freire, Maria (FNIH) [T] < b6 Lane, Cliff (NIH/NIAID) [E] b6 Parker, Ashley (NIH/OD) [E] <, b6 Anderson, James (NIH/OD) [E] b6 >
Cc: Wood, Gretchen (NIH/OD) [E] b6
Subject: ACTIV Daily Update 20200624.pptx

For this morning's war room, Wednesday June 24.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]
Sent: 11/30/2020 1:07:36 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]
Subject: ACTIV Call "War Room"
Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: Dial-In: **b6** Passcode: **b6**
Start: 12/2/2020 1:00:00 PM
End: 12/2/2020 1:30:00 PM
Show Time As: Busy
Recurrence: Weekly
Occurs every Wednesday from 8:00 AM to 8:30 AM effective 12/2/2020 until 3/10/2021.
Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rutter, Joni (NIH/NCATS) [E]

Optional Attendees: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Donna (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Gibbons, Gary (NIH/NHLBI) [E]

Extending to end of December

Dial-in: b6

Passcode: b6

Dr. Tabak as Leader: b6

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]

Attachments: ACTIV Daily Update 20201223.pptx

Location. Dial-in: **b6** Passcode: **b6**

Start: 12/23/2020 10:30:00 PM

End: 12/23/2020 11:00:00 PM

Show Time As: Tentative

Recurrence: (none)
every Wednesday from 8:00 AM to 8:30 AM

Required Attendees: Melencio, Cheryl (FNIH) [T]; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]

Optional Attendees: Gibbons, Gary (NIH/NHLBI) [E]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Menetski, Joseph (FNIH) [T]

Rescheduling due to a scheduling conflict

Dial-in: **b6**

Passcode: **b6**

Dr. Tabak as Leader: **b6**

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/13/2021 3:21:37 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210113.pptx
Attachments: ACTIV Daily Update 20210113.pptx

Please see attached slides for tomorrow's war room, Monday January 13.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/27/2021 3:35:45 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210127.pptx
Attachments: ACTIV Daily Update 20210127.pptx

Please see slides for tomorrow morning's war room call, Wednesday January 27.

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]

CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]

Start: 2/3/2021 1:00:00 PM
End: 2/3/2021 1:30:00 PM

Recurrence: (none)

Required Attendees: Melencio, Cheryl (FNIH) [T]; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rutter, Joni (NIH/NCATS) [E]

Optional Attendees: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Gibbons, Gary (NIH/NHLBI) [E]; Menetski, Joseph (FNIH) [T]

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/10/2021 2:00:06 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210210.pptx
Attachments: ACTIV Daily Update 20210210.pptx

Here are slides for tomorrow's war room, Wednesday, February 9.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/24/2021 3:19:07 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210224.pptx
Attachments: ACTIV Daily Update 20210224.pptx

Here are slides for tomorrow morning's war room, Wednesday February 24.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/3/2021 3:10:02 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: Update slides for tomorrow morning's war room, Wednesday March 3
Attachments: ACTIV Daily Update 20210303.pptx

In addition to the USG Tx slides sent earlier, here are our regular update slides for tomorrow's meeting. The Preclinical WG has included several supplementary slides detailing the first iteration of the 'TRACE Report,' a soon-to-be weekly variant report developed by NCBI and the TRACE WG. In addition to the PDF version of the report shown on the slides, the actual excel file and supplemental information is embedded in the top right corner of each slide in case you'd like to have a more detailed look.

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6 f.nih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852



From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/3/2021 2:15:16 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: Confidential for tomorrow morning's war room call
Attachments: 210301 research interagency meeting vsent 03_011.pdf

Dear war room colleagues:

I will be sending out the usual update slides either later tonight or first thing in the morning for tomorrow morning's war room call, Wednesday March 3. However I suspect we will rather want to spend a good deal of time discussing the implications of the findings from ACTIV-3 and their impact on the trial and on our prioritization efforts. The ACTIV Tx-Clinical WG co-chairs have in fact expressly asked that we address both of these issues tomorrow so we can provide them with some guidance as to how they should move forward.

As you will remember, we discussed on our last call the need to take a break from proactively prioritizing new candidate agents for ACTIV until we can take a step back and assess the overall landscape strategically. With regard to this, we have learned from Sarah Read of a cross-agency effort sponsored by USG Therapeutics to engage in just such a landscape analysis, looking broadly across all of the agents funded by USG to date. Please see attached the slides Sarah shared from the group's meeting this past Monday, March 1. I don't know if you have already seen these slides but I am sharing them with the usual cautions about confidentiality, though I understand a handful of NHers were on the call. I assume we will want to refer to them in our discussion about our prioritization efforts.

Regards,
David

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 3/10/2021 12:14:50 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Lancet on COVID R&D

Gerry, at least, should have at least researched this better, same with Victor. It will make for an interesting read.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, March 10, 2021 5:36 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> Anderson, James (NIH/OD) [E] <[REDACTED]> Rutter, Joni (NIH/NCATS) [E] <[REDACTED]> Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: Lancet on COVID R&D

Hi all,

You will want to find the right time to read this rather self-serving and poorly researched Lancet review of COVID R&D shortcomings. Keusch and Lurie, the first two authors, are explicitly seeking to have themselves named as co-chairs of a NAM panel on the same topic. The main figure omits any mention of ACTIV, which gets only brief mention in the text.

RADx, on the other hand, gets no mention at all. Apparently only CDC and BARDA are involved in diagnostics.

Sigh.

Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 3/10/2021 10:39:52 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: Letter to request confidential meeting
Attachments: b4

We'll need to discuss this today....

From: b6
Sent: Tuesday, March 9, 2021 2:59 PM
To: Collins, Francis (NIH/OD) [E] < b6 > Fauci, Anthony (NIH/NIAID) [E] < b6 >
Cc: b6
Subject: Letter to request confidential meeting

Dear Francis and Tony,

I communicate this letter from myself and other leaders at b4 (copied here) to request a confidential meeting with you (preferably the 5 of us).

We deeply appreciate the time and effort expended at this busy time to address this request which is communicated with all respect.

b4

b4

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 3/10/2021 10:35:55 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Lancet on COVID R&D
Attachments: COVID R&D Ecosystem. Lancet March 9, 2021.pdf

Hi all,

You will want to find the right time to read this rather self-serving and poorly researched Lancet review of COVID R&D shortcomings. Keusch and Lurie, the first two authors, are explicitly seeking to have themselves named as co-chairs of a NAM panel on the same topic. The main figure omits any mention of ACTIV, which gets only brief mention in the text.

RADx, on the other hand, gets no mention at all. Apparently only CDC and BARDA are involved in diagnostics.

Sigh.

Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/10/2021 3:40:08 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: ACTIV Daily Update 20210310.pptx
Attachments: ACTIV Daily Update 20210310.pptx

Here are the slides for tomorrow morning's war room, Wednesday, March 10.

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/24/2020 1:31:21 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Kent P Hassett [b6 Lilian Gonzalez b6 Andrew G Koustenis [b6 Janice Evans [b6 Jens Lundgren b6 Wentworth, Debby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dc146ea82bb402cb5c6596f43056347-wentw001.um]; Babiker, Ab b6 Ginde, Adit [b6 Ajay Nirula - Lilly b6 Moskowitz, Alan b6 Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Andrew Phillips [b6 b6 Gelijns, Annetine [b6 Birgit Grund (b6 [b6 b6 Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; b6 b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; b6 Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Ginny Kan b6 Baker, Jason [b6 jessica. b6 Jim Neaton [b6 Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]. b6 Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; b6 b6 Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Kozak, Manna (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Mark Polizzotto [b6 b6 ; Matthey, Michael [b6 Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Pau Klekotka - Lilly [b6 Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Roger Paredes [b6 Samuel Brown [b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shweta Sharma [b6 Thompson, Taylor, M.D. b6 b6 Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Davey, Victoria (b6 [b6 Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.cabr]; Larson, Gregg [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c8ba84a1994b458f9c6ce304ea6b93-larso279.um]; Peter Smith, M.D. (Thoracic Surgery) [b6 Katharina Krapp [b6 John Rule [b6 Aileen Ilaria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860a21fece5d4ff2b206b3d1856c06cf-AileenIlari]; Simpson, Shelly (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=371206262b394fecaab6f43a3a6f9de6-shsimpson]; Valiee, David [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=b6dd7891a2804584a9743714a242bd6b-digherokemp]; Hensley, Lisa (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=083ee40b073846fdabb00489a21d8247-hensleyle]; Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: ACTIV-3 Operations Team Meeting

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: ACTIV-3 Operations Team Meeting; Canceled: ACTIV-3 Operations Team Meeting; Untitled Attachment; Untitled Attachment

Location: <https://fnih.zoom>. **b6**

Start: 6/30/2020 3:00:00 PM

End: 6/30/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Weekly
every Tuesday from 11:00 AM to 12:00 PM

Required Attendees: Kent P Hassett; Lilian Gonzalez; Andrew G Koustenis; Janice Evans; Jens Lundgren; Wentworth, Debby;

(**b6** **b6** Ajay Nirula - Lilly; **b6** **b6**
Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips; **b6** **b6**
Birgit Grund (**b6** **b6** Lane, Cliff (NIH/NIAID) [E]; **b6**
b6 Higgs, Elizabeth (NIH/NIAID) [E]; **b6** Eric Hughes; Ginny Kan; Baker, Jason;
b6 Neaton, Jim; **b6** Judy Currier;
b6 Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA);
Miller, Marissa A (NIH/NHLBI) [E]; Mark Polizzotto; **b6** **b6** Proschan,
Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Harrigan, Rachel (HHS/IOS), Cavan,
Reilly; Roger Paredes; **b6** Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; Taylor Thompson;
b6 **b6** Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria
(**b6** Denning, Eileen; Larson, Gregg; Peter Smith, M D. (Thoracic Surgery); Katharina Krapp; John
Rule; Aileen Ilaria; Simpson, Shelly (NIH) [C]; Vallee, David; Charles T Benson; Robert Jan Benschop; Lei Shen; Jenny Y
Chien, Emmanuel Chigutsa; Daniel A Peterson; Daisy G Hartman; Jamie L Stack; Kristina Southern Dinkel; Susan R
Moriarty; Gourab Datta; Judith Anne Gallagher; Patricia L Brown-Augsburger; Biswas, Kousick; Harrington, Cristin A.;
Huyen Cao; Michelle Blanchard Vargas; Davina Evertse; Jamie Reese

Optional Attendees: Chen, Helen Q., Wachtel, Jonathan, Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Daniel Dawson Murray; **b6** Lisbeth Jørgensen; Nicole Engen, RH-FP-CHIP-ACTIV3-INSIGHT014, Tierney, John (NIH/NIAID) [E]; Marie Helleberg; Cate Carey; Vjecha, Michael; Hudson, Fleur, Pett, Sarah, Bitten Aagaard, Charlotte Bjernved Nielsen; Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; MacDonald, Leah (NIH) [C]; Ganapathy Gopalrathnam; Janele A Sabo; Carlos O Garner - Lilly; Tonya L Combs; Lori J Stephens; Lau, Chuen-Yen (NIH/NIAID) [E]; Herpin, Betsey (NIH/NIAID) [E]; Barrett Kevin (NIH/NIAID) [E]; Smolskis, Mary (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Osborne, Cynthia (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C]; Proffitt, Calvin (NIH) [C]; Hohn, Matt (NIH) [C]; **b6** McNay, Laura (NIH/NIAID) [E]; Pierson, Jerome (NIH/NIAID) [C]; Mock, Rebecca (NIH/NIAID) [E]; Segal Raim, Sharon (NIH) [E]; Miller, Tracey (NIH) [C]; Parrish, David (NIH/NIAID) [E]; Galcik, Michael (NIH) [C]; Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]; Baseler, Beth (NIH) [C]

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[b6 Bitten Aagaard [b6 Charlotte Bjernved Nielsen
[b6 Eccard-Koons, Vanessa (NIH) [C] [/o=ExchangeLabs/ou=Exchange
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(NIH/NIAD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[b6 Pierson, Jerome (NIH/NIAD) [C] [/o=ExchangeLabs/ou=Exchange Administrative
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b6 Ganapathy Gopalrathnam [b6 Herpin, Betsey
(NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Attachments: ACTIV TX-Clinical ACTIV-3 Operations Team Meeting Agenda 20200714.docx

Start: 7/14/2020 3:00:00 PM
End: 7/14/2020 4:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Kent P Hassett; Lilian Gonzalez; Andrew G Koustenis; Janice Evans; Jens Lundgren; Wentworth, Debby; b6 b6 Ajay Nirula - Lilly; b6 b6 Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips; b6 b6 Birgit Grund [b6 Lane, Cliff (NIH/NIAID) [E]; b6 b6 Higgs, Elizabeth (NIH/NIAID) [E]; Emilia.bagiel b6 b6 Ginny Kan; Baker, Jason; jessica. b6 b6 Neaton, Jim; b6 b6 Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA); Miller, Marissa A (NIH/NHLBI) [E]; Mark Polizzotto b6 ; b6 Proschan, Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Harrigan, Rachel (HHS/IOS); Cavan, Reilly; b6 Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; Taylor Thompson; b6 b6 Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria [b6 Denning, Eileen; Larson, Gregg; Peter Smith, M D. (Thoracic Surgery); Katharina Krapp; John Rule; Aileen M Ilaria, Simpson, Shelly (NIH) [C]; Vallee, David; Charles T Benson; Lei Shen; Jenny Y Chien; Emmanuel Chigutsa; Daisy G Hartman; Kristina Southern Dinkel; Susan R Moriarty; Gourab Datta; Judith Anne Gallagher; Patricia L Brown-Augsburger; Roger Paredes, Robert Jan Benschop; Jamie L Stack; Judy Currier; Daniel A Peterson; b6

Optional Attendees: Chen Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Daniel Dawson Murray; Lisbeth Jørgensen, Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014; Tierney, John (NIH/NIAID) [E]; Marie Heleberg; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard; Charlotte Bjermved Nielsen, Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; Tonya L Combs; Lori J Stephens; Barrett, Kevin (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C]; Hohn, Matt (NIH) [C]; b6 McNay, Laura (NIH/NIAID) [E]; Segal Raim, Sharon (NIH) [E]; Parrish, David (NIH/NIAID) [E]; Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Kenny, Dermot; Pierson, Jerome (NIH/NIAID) [C]; b6 Ganapathy Gopalrathnam; Herpin, Betsey (NIH/NIAID) [E]; Osborne, Cynthia (NIH) [C]; Janelle A Sabo; MacDonald, Leah (NIH) [C]; Galcik, Michael (NIH) [C]; Smoiskis, Mary (NIH/NIAID) [E]; Mock, Rebecca (NIH/NIAID) [E]; Proffitt, Calvin (NIH) [C]; Miller, Tracey (NIH) [C]; Hensley, Lisa (NIH/NIAID) [E]; Lau, Chuen-Yen (NIH/NIAID) [E]; Carlos O Garner - Lilly; Cate Carey; Eileen Denning

Dear ACTIV-3 Operations Team,

Please see below and attached and below a draft agenda for Tuesday's meeting. Please let me know if you have any slides you would like to present for your sections.

Agenda Topic	Time (EDT)	Duration	Facilitator
Opening			
• Review Agenda and Meeting Objectives	11:00am –11:05am	5 min.	Jim

FDA Comments	11:05am – 11:25am	20 mins.	Jens
Update from Lilly Team on Drug Supply Plan and Timetable	11:25am – 11:35am	10 min.	Aileen
cIRB Discussion	11:35am – 11:45am	10 min.	Laura
Site Registration	11:45am – 11:55am	10 min.	Eileen
Recap & Next Steps	11:55am – 12:00pm	5 min.	Jim / Stacey

Thanks,
Stacey

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Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
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[**b6** Baker, Jason [**b6** **b6** Jim Neaton
[**b6** Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group
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[**b6** **b6** Matthay, Michael [**b6** **b6** Proschan,
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[**b6** Samuel Brown [**b6** Read, Sarah (NIH/NIAID) [E]
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[**b6** Thompson, Taylor, M.D. **b6** **b6**
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(Thoracic Surgery) [**b6** Katharina Krapp [**b6** **b6** John Rule
[**b6** Aileen Ilaria [/o=ExchangeLabs/ou=Exchange Administrative Group
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Kousick [**b6** **b6** Harrington, Cristin A. [**b6** **b6** Huyen Cao
[**b6**

CC:

Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [b6 Carlos O Garner - Lilly [b6 Chen, Helen Q. [b6
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Danie Dawson Murray
 [b6 ; Lisbeth Jørgensen
 [b6 Nicole Engen [b6 RH-FP-CHIP-ACTIV3-INSIGHT014 [chip-
 activ3- b6 Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney],
 Marie Helleberg [b6]; Cate Carey [b6 Vjecha, Michael
 [b6 Hudson, Fleur [b6 Pett, Sarah [b6 Bitten Aagaard
 b6 Charlotte Bjørnved Nielsen [b6 Eccard-
 Koons, Vanessa (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=78c68caa1a3e4beb87d31199d1566e39-eccardvs]; Buehn, Molly (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=31119e48ee194b059ef26182e1fc706e-giambarl]; Ganapathy Gopalrathnam
 [b6 Tonya L Combs [b6 Lori J Stephens
 [b6 Lau, Chuen-Yen (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fd5052b609741d7a5560d4c68e30109-lauc]; Herpin, Betsey (NIH/NIAID) [E]
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f98ea94d0b549a9a20b14129958ffc8-herpinb]; Barrett, Kevin (NIH/NIAID)
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrettk2]; Smolskis, Marv
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddfa4630574f4cf794485d42e8f94f15-piersonjer]; Mock, Rebecca
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e7622242ed442a83557c86831344c5-sweetrl]; Segal Raim, Sharon (NIH)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fec017d4c0f44cea96f9b89b4138b02d-segalsb]; Miller, Tracey (NIH) [C]
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d7d2d97b44074abbca871c2e0fd2-parrishdb]; Galcik, Michael (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6dd7891a2804584a9743714a242bd6b-digherokemp]; Hensley, Lisa
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=083ee40b073846fdabb00489a21d8247-hensleye]; Baseler, Beth (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]

Subject: Canceled: ACTIV-3 Operations Team Meeting

Start: 7/21/2020 3:00:00 PM

End: 7/21/2020 4:00:00 PM

Show Time As: Free

Recurrence: (none)

Required Attendees: Robert Jan Benschop; Daniel A Peterson; Charles T Benson; Kent P Hassett; Lilian Gonzalez; Andrew G Koustenis;
 Janice Evans; Jens Lundgren; Wentworth, Debby; b6 b6 Ajay Nirula

- Lilly; b6 Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips;
b6 Birgit Grund (b6
b6 au; Lane, Cliff (NIH/NIAID) [E]; b6 b6 Higgs, Elizabeth
(NIH/NIAID) [E]; b6 b6 Ginny Kan; Baker, Jason;
b6 Neaton, Jim; b6 Judy Currier;
b6 Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA);
Miller, Marissa A (NIH/NHLBI) [E]; Mark Polizzotto; b6 b6 Proschan,
Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Harrigan, Rachel (HHS/IOS); Cavan,
Reilly; Roger Paredes; b6 Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; Taylor Thompson;
b6 b6 Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria
(b6 Denning, Eileen; Larson, Gregg; Peter Smith, M.D. (Thoracic Surgery); Katharina Krapp; John
Rule; Aileen M Ilaria; Simpson, Shelly (NIH) [C]; Vallee, David; Lei Shen; Jenny Y Chien; Emmanuel Chigutsa; Daisy G
Hartman; Jamie L Stack; Kristina Southern Dinkel; Susan R Monarty; Gourab Datta; Judith Anne Gallagher; Patricia L
Brown-Augsburger; Biswas, Kousick; Harrington, Cristin A.; Huyen Cao
Optional Attendees: Janelle A Sabo; Carlos O Garner - Lilly; Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers,
Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Daniel Dawson Murray;
b6 Lisbeth Jørgensen; Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014; Tierney, John
(NIH/NIAID) [E]; Marie Helleberg; Cate Carey; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard; Charlotte
Bjerved Nelsen; Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; MacDonald, Leah (NIH) [C]; Ganapathy
Gopalrathnam; Tonya L Combs; Lori J Stephens; Lau, Chuen-Yen (NIH/NIAID) [E]; Herpin, Betsey (NIH/NIAID) [E];
Barrett, Kevin (NIH/NIAID) [E]; Smoiskis, Mary (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Osborne, Cynthia (NIH) [C];
Voge, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C]; Proffitt, Calvin (NIH) [C]; Hohn, Matt (NIH) [C];
b6 McNay, Laura (NIH/NIAID) [E]; Pierson, Jerome (NIH/NIAID) [C]; Mock, Rebecca (NIH/NIAID)
[E]; Segal Raim, Sharon (NIH) [E]; Miller, Tracey (NIH) [C]; Parrish, David (NIH/NIAID) [E]; Gaick, Michael (NIH) [C];
Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]; Baseier, Beth (NIH) [C]

Hi All,

Cancelling per my other note.

Thanks,
Stacey

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Birgit Grund ([b6 [b6 b6 Lane, Cliff (NIH/NIAID) [E]
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 [b6 Baker, Jason [b6 b6 Jim Neaton
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c8ba84a1994b458f9c6ce304ea6b93-larso279.um] Peter Smith, M.D.
 (Thoracic Surgery) [b6 Katharina Krapp [b6 John Rule
 [b6 Aileen Ilaria [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [b6 Lei Shen [b6 Jenny Y Chien [b6
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 [b6
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e6b92ae902c4ad3b388e4bd2f6e12da-proffittch]; Hohn, Matt (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=758b9d09fbcd4fe39fcd97d9710ec787-hohnmj]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Pierson, Jerome (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddfa4630574f4cf794485d42e8f94f15-piersonjer]; Mock, Rebecca (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e762224ed442a83557c86831344c5-sweetrl]; Segal Raim, Sharon (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=9804c1bd1610470f91a91225da2f6182-trmi ler]; Parrish, David (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d7d2d97b44074abbca871c2e0fd2-parrishdb]; Galcik, Michael (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=493f88a89a3543c0b01df5473fd7c08a-mgalcik]; Dighero-Kemp, Bonnie (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b6dd7891a2804584a9743714a242bd6b-digherokemp]; Hensley, Lisa (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=083ee40b073846fdabb00489a21d8247-hensleyle]; Janelle A Sabo [b6] Kenny, Dermot [b6] Vogel, Susan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a18354e56c6c45d5b4a9701770890c81-svogel]; Chen, Helen Q. [b6] Wachtel, Jonathan [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [b6] Kurila, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurila]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Danie Dawson Murray [b6] Lisbeth Jørgensen [b6] Nicole Engen [b6] RH-FP-CHIP-ACTIV3-INSIGHT014 [chip-activ3-insight014.rigshosp talet@regionh.dk]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney], Marie Helleberg [b6]; Cate Carey [b6]; Vjecha, Michael [b6]; [b6]; Hudson, Fleur [b6]; Pett, Sarah [b6]; Bitten Aagaard [b6]; Charlotte Bjernved Nielsen [b6]; Eccard-Koons, Vanessa (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78c68caa1a3e4beb87d31199d1566e39-eccardvs], Buehn, Molly (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42fe6790581143a78a8b68e17fc600c0-buehnmj]; MacDonald, Leah (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31119e48ee194b059ef26182e1fc706e-giambarl]; Ganapathy Gopalrathnam [b6]; Carlos O Garner - Lilly [b6]; Tonya L Combs [b6]; Lori J Stephens [b6]; Lau, Chuen-Yen (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fd5052b609741d7a5560d4c68e30109-lauc]; Herpin, Betsey (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f98ea94d0b549a9a20b14129958ffc8-herpinb]; Barrett, Kevin (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Smolskis, Marv (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c85d8d087b304525ac6f2eab9fbb2d7-msmolskis]; Engel, Theresa (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e86305ea82754e65b67a63591ed867ba-engelt]; Osborne, Cynthia (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564d002f3a54421d90c6d86319e37c1f-osborneck]; Grace, Beth (NIH/NIAD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Proffitt, Calvin (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e6b92ae902c4ad3b388e4bd2f6e12da-proffittch]; Hohn, Matt (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=758b9d09fbed4fe39fcd97d9710ec787-hohnmj]; [b6]; McNay, Laura (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Pierson, Jerome (NIH/NIAD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddfa4630574f4cf794485d42e8f94f15-piersonjer]; Mock, Rebecca (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e7622242ed442a83557c86831344c5-sweetrl]; Segal Raim, Sharon (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fec017d4c0f44cea96f9b89b4138b02d-segalsb]; Miller, Tracey (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9804c1bd1610470f91a91225da2f6182-trmi ler]; Parrish, David (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d7d2d97b44074abbca871c2e0fdd2-parrishdb]; Galcik, Michael (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=493f88a89a3543c0b01df5473fd7c08a-mgalcik]; Dighero-Kemp, Bonnie (NIH/NIAD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6dd7891a2804584a9743714a242bd6b-digherokemp]; Hensley, Lisa (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=083ee40b073846fdabb00489a21d8247-hensleyle]; Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]

Subject: Canceled: ACTIV-3 Operations Team Meeting

Start: 7/28/2020 4:00:00 AM

End: 7/29/2020 4:00:00 AM

Show Time As: Free

Recurrence: (none)

Required Attendees: Daniel A Peterson; Kent P Hassett; Biswas, Kousick; Robert Jan Benschop; Jamie Reese; Lilian Gonzalez; Andrew G Koustenis; Janice Evans; Jens Lundgren; Wentworth, Debby; **b6** **b6**
Ajay Nirula - Lilly; **b6** Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips;
b6 Birgit Grund (**b6**
b6 Lane, Cliff (NIH/NIAID) [E]; **b6** **b6** Higgs, Elizabeth
(NIH/NIAID) [E]; **b6** **b6** Ginny Kan; Baker, Jason;
b6 **b6** Neaton, Jim; **b6** Judy Currier;
b6 **b6** Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA);
Miller, Marissa A (NIH/NHLBI) [E]; Mark Polizzotto; **b6** **b6** Proschan,
Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Harrigan, Rachel (HHS/IOS); Cavan,
Reilly; Roger Paredes; **b6** Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; Taylor Thompson;
b6 **b6** Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria
(**b6** Denning, Eileen; Larson, Gregg; Peter Smith, M.D. (Thoracic Surgery); Katharina Krapp; John
Rule; Aileen M Ilaria, Simpson, Shelly (NIH) [C]; Vallee, David; Charles T Benson; Lei Shen; Jenny Y Chien; Emmanuel
Chigutsa; Daisy G Hartman; Jamie L Stack, Kristina Southern Dinkel; Susan R Moriarty; Gourab Datta; Judith Anne
Gallagher; Patricia L Brown-Augsburger; Harrington, Cristin A.; Huyen Cao; Michelle Blanchard Vargas; Davina
Evertse
Optional Attendees: Janelle A Sabo; Kenny, Dermot; Vogel, Susan (NIH/NIAID) [E]; Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen
(FNIH) [T]; Desrosiers, Elizabeth A.; Kunilla, Michael (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Daniel Dawson
Murray **b6** ; Lisbeth Jørgensen; Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014; Tierney,
John (NIH/NIAID) [E]; Marie Helleberg; Cate Carey; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard;
Charlotte Bjørnved Nielsen; Eccard-Koons, Vanessa (NIH) [C]; Buenn, Molly (NIH) [C]; MacDonald, Leah (NIH) [C];
Ganapathy Gopalrathnam, Carlos O Garner - Lilly; Tonya L Combs; Lori J Stephens; Lau, Chuen-Yen (NIH/NIAID) [E];
Herpin, Betsey (NIH/NIAID) [E]; Barrett, Kevin (NIH/NIAID) [E]; Smolskis, Mary (NIH/NIAID) [E]; Engel, Theresa (NIH)
[C]; Osborne, Cynthia (NIH) [C]; Grace, Beth (NIH/NIAID) [C]; Proffitt, Calvin (NIH) [C]; Hohn, Matt (NIH) [C];
b6 McNay, Laura (NIH/NIAID) [E]; Pierson, Jerome (NIH/NIAID) [C]; Mock, Rebecca (NIH/NIAID)
[E]; Segal Raim, Sharon (NIH) [E]; Miller, Tracey (NIH) [C]; Parrish, David (NIH/NIAID) [E]; Galcik, Michael (NIH) [C];
Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]; Baseler, Beth (NIH) [C]

Dear ACTIV-3 Team,

As with the Protocol Team Meeting today, the ACTIV-3 leads have discussed and have decided that they would like to repurpose this time for another smaller group call to finalize some key components for launch.

Thanks,
Stacey

Join Zoom Meeting
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+ **b6** US (Tacoma)

Meeting ID: **b6**
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Find your local number: <https://fnih.zoom.us> **b6**

To: Eric Hughes [b6 Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Kent P Hassett [b6 Lilian Gonzalez [Lilian. b6 Andrew G Koustenis [b6 Janice Evans [b6 Jens Lundgren b6 Wentworth, Debby [b6 Babiker, Ab [b6 Ginde, Adit [b6 Ajay Nirula - Lilly [b6 Moskowitz, Alan [b6 Patterson, Amy (NIH/NHLBI) [E] [b6 Andrew Phillips [b6 Gelijs, Annetine [b6 Birgit Grund [b6 [b6 .au; Lane, Cliff (NIH/NIAID) [E] [b6 Higgs, Elizabeth (NIH/NIAID) [E] [b6 Ginny Kan [b6 Baker, Jason [b6 Jim Neaton [b6 Neaton, Jim b6 Judy Currier b6 Kozak, Marina (OS/ASPR/BARDA) Reineck, Lora (NIH/NHLBI) [E] [lora. b6 Mark Polizzotto [b6]; Miller, Marissa A (NIH/NHLBI) [E] [b6 Proschan, Michael (NIH/NIAID) [b6 Matthay, Michael [b6 Paul Klekotka - Lilly [E] [b6]; Aggarwal, Neil (NIH/NHLBI) [E] [b6 Cavan, Reilly [b6 Harrigan, Rachel (HHS/IOS) [b6 Samuel Brown [b6 Read, Sarah (NIH/NIAID) [E] [b6 Shweta Sharma [b6 Thompson, Taylor.M.D. [b6 rosenbey@nhlbi.nih.gov]; Davey, Victoria [b6 Denning, Eileen [b6 Larson, Gregg [b6 Peter Smith, M.D. (Thoracic Surgery) [b6 Katharina Krapp [b6 John Rule [b6 Aileen Ilaria [b6 Simpson, Shelly (NIH) [C] [b6 Vallee, David [davidv@tmg-drc.com]; Charles T Benson [b6 Robert Jan Benschop [b6 Lei Shen [b6 Jenny Y Chien [b6 Emmanuel Chigutsa [b6 Daniel A Peterson (daniel.peterson@lilly.com); Daisy G Hartman [b6 Jamie L Stack [b6 Kristina Southern Dinkel [b6 Susan R Moriarty [b6 Gourab Datta [b6 Judith Anne Gallagher [b6 Patricia L Brown-Augsburger [b6 Biswas, Kousick [b6 Harrington, Cristin A. [b6 Huyen Cao [b6 ; Michelle Blanchard Vargas [b6 Davina Evertse [Davina. b6 Jamie Reese [b6 Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]

CC: Chen, Helen Q. [b6 Wachtel, Jonathan [b6 Tountas, Karen (FNIH) [T] [b6 Desrosiers, Elizabeth A. [b6 Kurilla, Michael (NIH/NCATS) [E] [b6 Kenny, Dermot [b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Danie Dawson Murray [b6 emilia.bagiella@mountsinai.org; Lisbeth Jørgensen [b6 Nicole Engen [b6 RH-FP-CHIP-ACTIV3-INSIGHT014 [chip-activ3- b6 Tierney, John (NIH/NIAID) [E] b6 Marie Helleberg [b6 Vjecha, Michael [b6 Hudson, Fleur [b6 Pett, Sarah [b6 Bitten Aagaard b6 Charlotte Bjernved Nielsen [b6 Eccard-Koons, Vanessa (NIH) [C] b6 ; Buehn, Molly (NIH) [C] [buehnmj@niaid.nih.gov]; MacDonald, Leah (NIH) [C] [b6 Ganapathy Gopalrathnam [b6 Tonya L Combs [b6 Lori J Stephens [b6 Lau, Chuen-Yen (NIH/NIAID) [E] [chuen-yen. b6]; Herpin, Betsey (NIH/NIAID) [E] [b6 ; Barrett, Kevin (NIH/NIAID) [E] [b6]; Smolskis, Mary (NIH/NIAID) [E] b6 ; Engel, Theresa (NIH) [C] [theresa. b6 Osborne, Cynthia (NIH) [C] [b6 Vogel, Susan (NIH/NIAID) [E] b6 ; Grace, Beth (NIH/NIAID) [C] [b6 Proffitt, Calvin (NIH) [C] [b6 Hohn, Matt (NIH) [C] [b6]; McNay, Laura (NIH/NIAID) [E] [b6 Pierson, Jerome (NIH/NIAID) [C] b6 ; Mock, Rebecca (NIH/NIAID) [E] [b6 Segal Raim, Sharon (NIH) [E] [b6]; Miller, Tracey (NIH)

[C] [b6 Parrish, David (NIH/NIAID) [E] b6 Galcik, Michael (NIH) [C]
[b6 ih.gov]; Dighero-Kemp, Bonnie (NIH/NIAID) [C] [b6 Hensley, Lisa
(NIH/NIAID) [E] [b6 Cate Carey [b6 Carlos O Garner - Lilly
b6]; Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]; Janelle A Sabo
[b6

Start: 8/4/2020 3:00:00 PM

End: 8/4/2020 4:00:00 PM

Recurrence: (none)

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Kent P Hassett

[b6 Lilian Gonzalez [b6 Andrew G Koustenis
[b6 Janice Evans [b6 Jens Lundgren b6
Wentworth, Debby [b6 Babiker, Ab [b6 Ginde, Adit
[b6 Ajay Nirula - Lilly [b6 Moskowitz, Alan
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Birgit Grund [b6 [b6 Lane, Cliff (NIH/NIAID) [E]
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[b6]; Miller, Marissa A (NIH/NHLBI) [E] [b6 Mark Polizzotto
[b6 Matthay, Michael [b6 Proschan, Michael (NIH/NIAID)
[E] [b6]; Aggarwal, Neil (NIH/NHLBI) [E] [b6 Paul Klekotka - Lilly
[b6 Harrigan, Rachel (HHS/IOS) [b6 Cavan, Reilly
[b6 .edu]; Roger Paredes [b6 Samuel Brown [b6 Read,
Sarah (NIH/NIAID) [E] [b6 Shweta Sharma [b6 Thompson, Taylor.M.D.
[b6 b6 b6 Rosenberg, Yves (NIH/NHLBI) [E]
[b6 ; Davey, Victoria [b6 [b6 Denning, Eileen
[b6 Larson, Gregg [b6 Peter Smith, M.D. (Thoracic Surgery)
[b6 Katharina Krapp [b6 John Rule [b6 Aileen
Ilaria [b6 Simpson, Shelly (NIH) [C] [b6 Vallee, David b6
Charles T Benson [b6 Robert Jan Benschop [b6 Lei
Shen [b6 Jenny Y Chien [b6 Emmanuel Chigutsa
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[b6 Huyen Cao [b6 ; Michelle Blanchard Vargas
[b6 Davina Evertse [Davina. b6 Jamie Reese
[b6 b6

CC: Chen, Helen Q. [b6 Wachtel, Jonathan [b6 Tountas, Karen (FNIH) [T]
[b6 Desrosiers, Elizabeth A. [b6 Kurilla, Michael (NIH/NCATS) [E]
[b6 Kenny, Dermot [b6 Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Danie Dawson Murray
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activ3- b6 Tierney, John (NIH/NIAID) [E] b6 Marie
Helleberg [b6 Vjecha, Michael [b6]; Hudson, Fleur
[b6 Pett, Sarah [b6 Bitten Aagaard [b6 Charlotte
Bjervned Nielsen [b6 Eccard-Koons, Vanessa (NIH) [C] b6
[b6]; Buehn, Molly (NIH) [C] [b6 MacDonald, Leah (NIH) [C]
[b6]; Ganapathy Gopalrathnam [b6 Tonya L Combs
[b6 Lori J Stephens [b6 Lau, Chuen-Yen (NIH/NIAID) [E] b6
[b6 Herpin, Betsey (NIH/NIAID) [E] [b6 Barrett, Kevin (NIH/NIAID) [E]
[b6 Smolskis, Mary (NIH/NIAID) [E] [b6 Engel, Theresa (NIH) [C]
[b6 Osborne, Cynthia (NIH) [C] [b6 Vogel, Susan (NIH/NIAID) [E]
[b6 Grace, Beth (NIH/NIAID) [C] [b6 Proffitt, Calvin (NIH) [C]
[b6 Hohn, Matt (NIH) [C] [b6]; b6 McNay, Laura
(NIH/NIAID) [E] [b6 Pierson, Jerome (NIH/NIAID) [C] [b6]; Mock, Rebecca
(NIH/NIAID) [E] [rebecca b6 Segal Raim, Sharon (NIH) [E] [b6]; Miller Tracey (NIH)
[C] [b6 Parrish, David (NIH/NIAID) [E] [b6 Galcik, Michael (NIH) [C]

[b6 Dighero-Kemp, Bonnie (NIH/NIAID) [C] [bonnie.d b6 Hensley, Lisa
(NIH/NIAID) [E] b6 Cate Carey [b6 Carlos O Garner - Lilly
b6]; Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]; Janelle A Sabo
[b6]

Start: 8/25/2020 3:00:00 PM
End: 8/25/2020 4:00:00 PM

Recurrence: (none)

From: Rashid, Kamilah (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=58CE52E578B74034834AA866085C8677-RASHIDKL]
Sent: 6/4/2020 6:43:21 PM
To: Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2bf13-walsher]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Everyone,

My schedule is open except between 12 PM – 1 PM.

Best,
Kamilah

Kamilah Rashid, PharmD
Health Science Policy Analyst
Immediate Office of the Director
National Institutes of Health

M: b6
P: b6
E: b6



From: "Walsh, Elizabeth (NIH/OD) [E]" <b6>
Date: Thursday, June 4, 2020 at 2:30 PM
To: "Parker, Ashley (NIH/OD) [E]" <b6> "Cutillo, Christine (NIH/NCATS) [E]" <b6>
Cc: "Rashid, Kamilah (NIH/OD) [E]" <b6>
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi all,
I'm available in the 2 3:30 time slot.

Best,
Beth

From: "Parker, Ashley (NIH/OD) [E]" <b6>
Date: Thursday, June 4, 2020 at 2:22 PM
To: "Cutillo, Christine (NIH/NCATS) [E]" <b6>
Cc: "Rashid, Kamilah (NIH/OD) [E]" <b6> "Walsh, Elizabeth (NIH/OD) [E]" <b6>
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

It was great touching base this morning and I wish we had more time. As promised, let's schedule a follow-up for tomorrow or early next week to discuss thoughts underway for connecting the dots between the COVID candidates/technologies portal and NCATS/ACTIV/Deloitte's efforts. It would be great for Beth and Kamilah to join, they lead the COVID-19 candidates/tech portal and want to ensure we are in sync as there is a request/need to track compounds after they are submitted by companies etc. in this portal.

I'm available tomorrow between 1:30-3:30pm if this works for everyone. I can also be available after 4:15pm tomorrow.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 10:18 AM
To: Cutillo, Christine (NIH/NCATS) [E] <[REDACTED]> b6
Cc: Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> b6 Rashid, Kamilah (NIH/OD) [E]
<[REDACTED]> b6 Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

Happy to chat – invite has been sent to discuss this morning.

Thanks,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] [REDACTED] b6
Sent: Thursday, June 4, 2020 10:11 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Cc: Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6 >; Rashid, Kamilah (NIH/OD) [E]
[REDACTED] b6 >; Walsh, Elizabeth (NIH/OD) [E] [REDACTED] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

I'm not sure I understand what you mean by a few of your questions and comments. I think there is some misunderstanding about items. Would you be available sometime this morning to discuss? I can be available anytime before 12p.

What training and portal are you referring to? We have supported a few different ones, so your help on clarifying this will enable me to understand your questions better.

For items received through the OD portal – Deloitte/ACTIV has been planning on tracking the status of those that ACTIV receives, not however any of the items that are sent to RADx nor the ICs since it's not in their remit.

For the ACTIV compounds survey – this is just about to go out (it sounded like the emails were being finalized yesterday) and we starting discussing with the FNIH/Deloitte ACTIV teams about the process/procedure once they receive new compound suggestions from the OD portal (e.g., likely would need to be prioritized and then trigger the ACTIV compounds survey being sent). It sounds like this still needs to be determined, but Nina/Ben/Dina have it on their radar as an item to tackle next. The thing that Deloitte first needs to hash out is the data flow/schematic so that we can appropriately determine all the processes and procedures.

Best,
Christine

Christine Cutillo, MMCI
Special Assistant to the Director
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health
Phone: b6
b6

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, June 3, 2020 7:42 PM
To: Cutillo, Christine (NIH/NCATS) [E] b6
Cc: Austin, Christopher (NIH/NCATS) [E] b6 >; Rashid, Kamilah (NIH/OD) [E] b6 >; Walsh, Elizabeth (NIH/OD) [E] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

As promised, please see the attached agents received by the COVID-19 portal May 23-May 29 and were selected by the NIH SMEs to move forward for ACTIV. 54 submissions were received in total.

NIH OD (Kamilah and Beth from Tara's team and myself) have a training scheduled tomorrow to learn more about the dashboard NCATS has funded. I still haven't quite yet wrapped my head around how all these things will be tracked. Francis is interested in knowing how we will be able to track all compounds that come in to the COVID-19 portal that is then shared with RADx, ACTIV, ICs, etc. – what happens to all of them if asked what happened with compound X? I assume this is the million dollar project.

I'm also aware if the 2nd tier portal/survey ACTIV and NCATS has developed for additional information but still not clear on how this will be handled for logistical/process purposes.

Christine – it would be useful if we could chat for 15-30 mins this week to touch base and discuss. Please let me know if your schedule allows.

Thank you,
Ashley

From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Monday, June 1, 2020 8:57 AM
To: Parker, Ashley (NIH/OD) [E] < b6 Cutillo, Christine (NIH/NCATS) [E] b6
Cc: Adam, Stacey (FNIH) [T] < b6 Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
b6 >; Rashid, Kamilah (NIH/OD) [E] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

Many thanks – this is just what we need and will be very useful for ensuring that our inventory process is comprehensive. In addition, the way the data are presented is quite good and will help us in our efforts to determine how to do that broadly.

All best,

Chris

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Sunday, May 31, 2020 8:48 PM
To: Austin, Christopher (NIH/NCATS) [E] < b6 > Cutillo, Christine (NIH/NCATS) [E]
b6
Cc: Adam, Stacey (FNIH) [T] b6 Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
Rashid, Kamilah (NIH/OD) [E] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Chris and Christine,

Got it! Attached is the spreadsheet of emails received between early March and late May. With the [NIH COVID 19 Candidates and Technologies Portal](#) now live, all emails relevant to ACTIV are being routed there for submission and we've only had one round of review by the NIH COVID portal review group for inquiries received May 14 22 – please see 2nd attachment. The review group received a total of 58 submissions, 15 were determined to have potential – 8 of which are relevant to ACTIV.

Christine – I will cc you when we receive these each week. The 2nd attachment will provide an idea of the data fields used for the COVID portal.

We are still working on a process for receiving candidates from BARDA that have been reviewed by NIH staff who attend the BARDA held CoronaWatch meetings. Hopefully we can easily integrate those into a single spreadsheet to be shared. I've been working closely with Kamilah on Tara's team with this and we've discussed some of the questions outlined below –cc'ing Kamilah in case she has anything to add.

Thanks,
Ashley

From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Sunday, May 31, 2020 11:18 AM
To: Parker, Ashley (NIH/OD) [E] b6
Cc: Cutillo, Christine (NIH/NCATS) [E] < b6 > Adam, Stacey (FNIH) [T] b6 Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

Thank you for all your efforts and sorry for the delay in getting back to you; as you know, ACTIV has been busy!

Just want to clarify the portals issue. You're right that Larry has brought Deloitte in to do a larger assessment of COVID informatics needs since many ICs have asked for solutions; he and Susan G are leading that and there is a WG of us ICs that will help. The immediate portal need is for ACTIV, to allow their prioritization teams, coordinated by Joe Menetski and Stacey Adam at FNIH, to have all the possible assays and agents to consider for inclusion. Christine Cutillo is working

very closely with the FNIH and Deloitte teams to bring all the entries from many different portals into a single database. We want to be sure to include the entries that the OD portal is getting.

If you are sending all the submissions from the OD portal to FNIH already, the issue may have been solved indirectly already since the combined NIH-FNIH-Deloitte group has the OD entries. But it does appear quite odd for the NIH IC partners on ACTIV (coordinated by Christine Cutillo) to not receive NIH data from the OD, but rather have to get it from FNIH. Hence my request to simply get the information directly from you. To prevent any entries from falling through the cracks, pls begin copying Christine on the information you share with FNIH each week.

Hope this makes sense. Thanks,

Chris

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, May 20, 2020 7:12 PM
To: Cutillo, Christine (NIH/NCATS) [E] b6, Adam, Stacey (FNIH) [T] < b6 Anderson, James (NIH/OD) [E] < b6
Cc: Aust.n, Christopher (NIH/NCATS) [E] b6, Santangelo, George (NIH/OD) [E] b6 >; Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
Gladman, Jordan (NIH/OD) [E] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

There have been a few updates since the note from Chris on Sunday and I want to clarify a few things.

- We have not received any spreadsheets from BARDA with data fields – one of the NIAID POs who is a reviewer for the BARDA CoronaWatch meetings shared a PDF short list of compounds for ACTIV Tx clinical WG to consider – this is what I shared on Friday.
- The spreadsheet OD has managed prior to the launch of the COVID portal only contains emails (contact info, brief descriptor i.e. vaccine, preclinical interest, etc.) Dr. Collins has received as it relates to ACTIV. We have shared these with FNIH each week to sort and share relevant information with the WGs ES has sent a standard response to those emails and in some cases FNIH has followed up when relevant. I think only a handful may have been fully useful and fleshed out.
- Tara's team is leading the NIH portal efforts – yes, data fields are closely aligned with BARDA. Also, Tara's team has a review process for queries received through this portal and would have the spreadsheet of data fields you are looking for – it may be a good idea to touch base with Tara and her team to ensure the efforts outlined below are aligned.
- As of yesterday, my understanding was Dr. Tabak made a decision to coordinate these efforts via a small IC data group and next steps are to bring in PM from Deloitte as you've indicated below to access all of the needs including RADx, ACTIV, and others before making a final decision to merge information from all portals. My take on this was to pause for the moment but I defer to Chris on the action items below.

I hope this is useful.

Best,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] b6
Sent: Wednesday, May 20, 2020 3:37 PM

To: Adam, Stacey (FNIH) [T] < b6 Parker, Ashley (NIH/OD) [E] < b6 Anderson, James (NIH/OD) [E] b6
Cc: Austin, Christopher (NIH/NCATS) [E] b6 >; Santangelo, George (NIH/OD) [E] b6 >; Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Dear All,

Wanted to provide you with an update – we have been working with Andrew Derr (Deloitte NIH contract) to get someone by tomorrow/end of the week to start working on this. More detailed steps are included below in addition to a few questions. For clarification – which spreadsheet/database contains the appropriate data fields that should be propagated/mapped for each of the others (e.g., the BARDA submissions or the ACTIV compound spreadsheet)? I believe the NIH portal was built based on the BARDA submission data fields, but if we're ultimately aiming to connect to the ACTIV compound spreadsheet then potentially we should build toward that now when connecting these unsolicited submissions. Also, where do the submissions received via the NIH portal live and/or will a spreadsheet be sent at some periodicity? I apologize if these are questions that have already been addressed, but I haven't received that information yet.

Best,
Christine

-
1. Merge relevant information from all portals mapped to consistent data fields into the NIH db ("relevant" means submissions relevant to the ACTIV process; some NIH portals will contain COVID-related but not ACTIV-relevant entries)
 - a. BARDA submissions – *is this the template of data fields that all others should be aligned with or should they be aligned with the data fields contained within the ACTIV compound spreadsheet?*
 - b. OD received submissions (prior to implementation of portal) – *Ashely*, do you have this spreadsheet and have the data fields already been aligned with BARDA and/or the NIH portal?
 - c. NIAID submissions – spreadsheet provided by Alan Embry (contact him to ensure on same page); data fields need to be mapped/aligned
 - d. NCATS submissions – data fields need to be mapped/aligned
 2. Eliminate duplicate entries (sent by the same person to multiple portals)
 - a. Via name/email matching
 3. Send email to those not submitted through the NIH portal
 - a. Permission to integrate into ACTIV prioritization
 - b. Fill out survey – *either compound RedCap survey or NIH portal depending on answer to initial question – thinking it's the former?*
 4. Collate all into single db/spreadsheet for ACTIV/TransNIH use
 5. Set up process for updating submissions received via NIH portal and other sources
 - a. *Where do the submissions received via the NIH portal live and/or will a spreadsheet be sent at some periodicity?*
 - b. *Has an email been sent out alerting folks at NIH to direct external inquiries to this portal or do we need to set up a process for receiving new submissions from e.g., NIAID?*

Christine Cutillo, MMCI
Special Assistant to the Director
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health

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From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Sunday, May 17, 2020 12:37 PM
To: Adam, Stacey (FNIH) [T] <b6>; Parker, Ashley (NIH/OD) [E] b6 >; Cutillo, Christine (NIH/NCATS) [E] <cutill b6>; Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6 >; Anderson, James (NIH/OD) [E] b6 >; Santangelo, George (NIH/OD) [E] b6
Subject: FW: BARDA Corona Watch | Therapeutic Candidates for Consideration

All,

We made good headway last week on a strategy to eliminate redundant entries from different submission portals to enable a complete and nonredundant list of entries to be provided to Stacey's group for wave 2 and wave 3 prioritization. The list from BARDA enclosed, and the analysis Stacey did on it, is just the kind of information we have, or need to extract, from the NIAID portal, NCATS portal, Bldg 1 portal, intramural portal, and nonpublic OPA db. The steps defined are:

1. Merge relevant information from all portals into the NIH db ("relevant" means submissions relevant to the ACTIV process; some NIH portals will contain COVID-related but not ACTIV-relevant entries)
2. Eliminate duplicate entries (sent by the same person to multiple portals) by name/email matching
3. Depending on whether the portal required the submitter to grant permission for sharing internal to NIH and/or with ACTIV (latter, non-NIH for evaluation purposes only, under NDA), send submitter an email asking for such permission to be granted, and
4. Depending on whether the submitter included the fields needed by Stacey's group for initial evaluation, in same email ask the submitter to supply the missing information
5. Collate responses and deliver to Stacey.

Christine, please devise a sequential workflow and enlist those you need for help.

Many thanks to all the portal owners for helping to create a filter funnel that will get the relevant information to ACTIV.

Chris

From: Adam, Stacey (FNIH) [T] b6
Sent: Saturday, May 16, 2020 11:05 AM
To: Freire, Maria (FNIH) [T] <b6>; Collins, Francis (NIH/OD) [E] b6 >
Cc: Parker, Ashley (NIH/OD) [E] b6 >; Tabak, Lawrence (NIH/OD) [E] b6 >; Lane, Cliff (NIH/NIAID) [E] b6 >; Austin, Christopher (NIH/NCATS) [E] b6 >; Anderson, James (NIH/OD) [E] b6 >; Wholley, David (FNIH) [T] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria,

Of the top three candidates we selected: Abatacept (CTLA-IgG1 Fusion), Cenicriviroc (CCR2/5 inhibitor), and infliximab (TNF-alpha antagonist). Only the TNF inhibition seems to appear on the BARDA list.

Of our top 39 candidates that got scored, many MOAs were working to address some of the same issues that those on the BARDA list seem to target, such as anticoagulants, though those we reviewed and selected were largely already

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available in hospitals so they could be easily and quickly deployed for the NHLBI/NINDS trial. BARDA's anticoagulants seem to be next generation and working through slightly different MOAs. Also, we had number of anti-inflammatory targeting MOAs on our list that don't appear on the BARDA list, such as anti-IL17, RASP inhibition, PDE4 inhibition, GSK5 inhibition, and others. But again, both groups trying to get at the same issue, just through different points in the inflammation pathway. The one thing I notice is the BARDA list only seems to have 1 antiviral on their list, whereas we have about 9, and while we didn't prioritize them first, we did think some would likely be high priority for our next wave of trials with a slightly different design.

Again, I hope this is helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct **b6** Mobile: **b6**

From: Freire, Maria (FNIH) [T] <**b6**>
Sent: Saturday, May 16, 2020 10:51 AM
To: Adam, Stacey (FNIH) [T] **b6**; Collins, Francis (NIH/OD) [E] **b6**
Cc: Parker, Ashley (NIH/OD) [E] **b6**; Tabak, Lawrence (NIH/OD) [E] **b6**;
Lane, Cliff (NIH/NIAID) [E] **b6**; Austin, Christopher (NIH/NCATS) [E] **b6**;
Anderson, James (NIH/OD) [E] **b6**; Wholley, David (FNIH) [T] **b6**
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Thank Stacey- very helpful. How about the converse: are there MOA on the WG list that are not on this one? M.

From: "Adam, Stacey (FNIH) [T]" **b6**
Date: Saturday, May 16, 2020 at 9:40:55 AM
To: "Freire, Maria (FNIH) [T]" **b6**; "Collins, Francis (NIH/OD) [E]" **b6**
Cc: "Parker, Ashley (NIH/OD) [E]" **b6**; "Tabak, Lawrence (NIH/OD) [E]" **b6**;
"Lane, Cliff (NIH/NIAID) [E]" **b6**; "Austin, Christopher (NIH/NCATS) [E]" **b6**;
"Anderson, James (NIH/OD) [E]" <**b6**> "Wholley, David (FNIH) [T]" **b6**
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria and Francis,

As these compounds largely did not have information in the public domain for ongoing trials or major preclinical experiments in SARS-CoV-2 when we did our first pull 5 weeks ago, most, if not all, would not have been on our list.

However, looking at the mechanisms of action (MOA), we did have a number of agents that have same or similar MOAs, including IL-6 inhibition (3 agents on our review list) and JAK/STAT inhibitors (4 on our list). Both of these classes our group chose not to select for the first large confirmatory trial we were designing because their MOAs were being studied in well designed trials by other groups.

There are some MOAs that were not on our original list, such as IL-15 inhibition, though we did have many other IL inhibitors, including IL-1, 6, and 17. The Syk inhibitors are also a new MOA that did not appear in the first 170 of clinically ready agents.

I hope this information helps.

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [REDACTED] b6 Mobile: [REDACTED] b6

From: Freire, Maria (FNIH) [T] [REDACTED] b6

Sent: Saturday, May 16, 2020 10:03 AM

To: Collins, Francis (NIH/OD) [E] [REDACTED] b6

Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6> Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6

Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 >; Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6 ;

Anderson, James (NIH/OD) [E] [REDACTED] b6 >; Wholley, David (FNIH) [T] [REDACTED] b6 ; Adam,

Stacey (FNIH) [T] [REDACTED] b6

Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Good morning Stacey. Could you please take a look and let us know? Many thanks, M.

On May 16, 2020, at 8:46 AM, Collins, Francis (NIH/OD) [E] [REDACTED] b6 > wrote:

Interesting. Would the therapeutics on this list have been on the list of 170 that the Therapeutics Clinical WG was prioritizing?

FC

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6

Sent: Friday, May 15, 2020 2:49 PM

To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 >; Lane,

Cliff (NIH/NIAID) [E] [REDACTED] b6 Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6 >, Anderson,

James (NIH/OD) [E] [REDACTED] b6 Wholley, David (FNIH) [T] [REDACTED] b6 >; Freire, Maria (FNIH)

[T] [REDACTED] b6

Cc: Adam, Stacey (FNIH) [T] <[REDACTED] b6>

Subject: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi all,

Attached is a list of compounds shared by one of NIAID's program officers, Steve Smiley who is a reviewer/participant assigned to the **therapeutics Tech Watch (now CoronaWatch) meetings** at BARDA. Steve indicated they have ~10 meetings per week and there are other NIAID experts who join these. He suggested NIH reps who attend the BARDA meetings could assist with sharing compounds with ACTIV – recent focus has been on therapeutic products for infected outpatients for the DAIDS ACTG network but he indicated many products are better suited to phase 2 testing in hospitalized patients.

Steve also suggested we develop a short script for the NIH POCs who attend the BARDA Corona Watch meetings and use this as an opportunity to inform companies about ACTIV. We could link them to our vetting process (i.e. new portal) and/or feed them directly to the working groups. It seems prior to ACTIV, NIAID has used these Corona watch meetings to look for opportunities that would be useful for NIAID networks – Cliff likely has more insight here. The opportunity to expand and be inclusive of ACTIV seems like the right path and an opportunity to stay connected with what comes through BARDA.

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Would this be something of interest to the group?

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGE LABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/31/2020 11:44:44 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Kirchoff, Matthew (NIH/NIAID) [E] [b6 Mamta Jain [b6 Jens Lundgren
[b6 Neaton, Jim [b6 Harrigan, Rachel (HHS/IOS)
[b6 Higgs, Elizabeth (NIH/NIAID) [E] [b6 McNay, Laura (NIH/NIAID) [E]
[b6]; Samuel Brown [b6 [b6 [b6
[b6 Harrington, Cristin A. [b6 Kan, Virginia [b6
Biswas, Kousick [b6 Victoria Davey [b6 Baracco Lira, Gio J (Miami VA)
[b6 Baracco, Gio J, M.D. [b6 Lichtenberger, Paola N. (Miami VA)
[b6 Bhattacharya, Debika [b6 Krah, Scott E.
[b6 Lim, Kokkheang [b6 Williams, Allison E. [b6
Ratliff, Whitney A. [b6 Buck, Theresa A. [b6 Taylor Thompson
[TTHOMPSON [b6 annetine.gel [b6 [b6 Baker,
Jason [b6 Catherine Hough [b6]; Judith Anne Gallagher
[b6 Katharina Krapp [katharina.krapp@regionh.dk]; Daniel Dawson Murray
[b6 Sueiro, Melyssa (Miami VA) [b6 Peter Smith, M.D.
(Thoracic Surgery) [b6 Christina Chang [b6 Mark Polizzotto
[b6 .au]; Parker, CAPT Sheri (HHS/IOS) [b6 Christine Wenner
[b6 ID-Markowitz, Norman [b6 Gardner, Edward M MD
[b6 Sanchez, Adriana [b6]; Kent P Hassett
[b6 Lilian Gonzalez [b6 Andrew G Koustenis
[b6 Janice Evans [b6 Wentworth, Debby [b6
[b6 Ajay Nirula - Lilly [b6 [b6 Patterson, Amy
(NIH/NHLBI) [E] [b6 Andrew Phillips [b6 B rgit Grund
([b6 [b6 Lane, Cliff (NIH/NIAID) [E] [b6 [b6
[b6 [b6 [b6 [b6
[b6 [b6 Reineck, Lora (NIH/NHLBI) [E]
[b6 Kozak, Manna (OS/ASPR/BARDA) [b6 [b6 Miller, Marissa A (NIH/NHLBI)
[E] [b6 ; [b6 [b6 Proschan, Michael (NIH/NIAID) [E]
[b6]; Aggarwal, Neil (NIH/NHLBI) [E] [b6 Paul Klekotka - Lilly
[b6 Cavan, Reilly [b6 Roger Paredes [b6]; Read,
Sarah (NIH/NIAID) [E] [b6 Shweta Sharma [b6 [b6
[b6 Rosenberg, Yves (NIH/NHLBI) [E] [b6 [b6 Davey, Victoria
([b6 [b6 Aileen Ilaria [b6 [b6 Charles T Benson
[b6 Robert Jan Benschop [b6 [b6 Lei Shen [b6
Jenny Y Chien [b6 [b6 Emmanuel Chigutsa [b6 [b6]; Daniel A
Peterson [b6 [b6 Daisy G Hartman [b6 [b6 Jamie L Stack
[b6 Kristina Southern Dinkel [b6 [b6 Susan R Moriarty
[b6 Gourab Datta [b6 [b6 Patricia L Brown-Augsburger [brown-
augsburger_ [b6 Denning, Eileen [b6 [b6 Larson, Gregg [b6 John
Rule [b6 Teitelbaum, Marc (NIH) [C] [b6 [b6 Cahill, Kelly (NIH/NIAID) [E]
[b6 Mack, Michael J [b6 [b6 Moquete, Ellen
[b6 Marks, Mary [b6 [b6 Gupta, Lopa
[b6 O'sullivan, Karen [karen. [b6 [b6 Vailee, David [b6
Birgit Grund [b6 [b6 [b6 [b6 [b6
[b6 [b6 [b6 [b6 [b6
[b6 [b6 [b6 [b6 [b6
[b6 [b6 [b6 [b6 [b6
[b6 Gregory, Adam [b6 [b6 [b6 [b6
[b6 Fenton, Kathleen (NIH/NHLBI) [E] [b6 [b6]; Taddei-Peters, Wendy
(NIH/NHLBI) [E] [b6 [b6]; Collins, Francis (NIH/OD) [E] [b6 [b6 Whol ey, David (FNIH)
[T] [b6 [b6 Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]

CC: Sarah Doernberg [b6 David Lye [b6 Driver, Brian
[b6 Accardi, Evan [evan.acca b6 Prekker, Matthew
[b6 Mackedanz, Shan [Shari. b6 Gonzalez, Luis A. (Miami VA)
[b6 r]; Washburn, Katrina B. (Miami VA) [b6]; Ramos, Carol F. (Miami VA)
[b6 Kathleen Lane, RN, BSN [kathleen. b6 Beth Hollister
[b6 Vidales, Elizabeth [b6 Alyssa Hughes
[b6 Sturgill, Jamie [b6 Beverly, Jennifer b6 Moss, Marc
[b6 Rebekah K. Peacock [b6 Mehkri, Omar [b6
Jenna Davis b6 Chang, Steven Y. [b6 Valerie Aston
[b6 Gray, Christopher S [ch b6 Roth, Megan
[b6 Dudley, Adam [b6 Nick Johnson [b6 Romaine,
Connie [b6 Liu, Kathleen Don [b6 Sarah A Sterling [b6
Jarrod Mosier [b6 Rosseto,Elinita (BIDMC - Emergency Medicine)
[b6 Hyzy, Robert (Bob) [b6 Rice, Todd [todd. b6 D.
Clark Files b6 Duggal, Abhijit [b6 DiFiore, Sara
[b6 Parry, Blair Alden [b6 Thomas Mazzocco
[b6 Utsav Nandi [b6 Agarwal, Trisha [b6
Talmor,Daniel S (HMFP - Anesthesia) [b6 Higgins, Carrie
[b6 Dugar, Siddharth [b6 Kozikowski, Lori-Ann [Lori-
Ann. b6 Bienstock, Karen (NIH/NHLBI) [E] [karen. b6 Akram Khan
[b6 Christine A. Lord [b6 Sahoo, Debasis [b6 Jens Ulrik Stæhr
Jensen [b6 Steingrub, Jay [b6 De Souza, Les ey
[b6 Sandi, Marie [b6 b6 Lisbeth
Jørgensen [lisbeth. b6 Nicole Engen [b6 RH-FP-CHIP-ACTIV3-INSIGHT014
[b6 Tierney, John (NIH/NIAID) [E] b6 Marie
Helleberg [b6 Vjecha, Michael [b6]; Hudson, Fleur
[b6 Pett, Sarah [b6 Bitten Aagaard [b b6 Charlotte
Bjervned Nielsen b6 Eccard-Koons, Vanessa (NIH) [C] [b6
[b6]; Buehn, Molly (NIH) [C] [b6 MacDonald, Leah (NIH) [C]
[b6]; Ganapathy Gopalrathnam b6]; Janelle A Sabo
[b6]; Tonya L Combs b6]; Lori J Stephens [b6 Lau, Chuen-Yen
(NIH/NIAID) [E] b6], Herp.n, Betsey (NIH/NIAID) [E] [b6 Barrett, Kevin
(NIH/NIAID) [E] [b6 Smolskis, Mary (NIH/NIAID) [E] [b6 Engel, Theresa
(NIH) [C] b6 Osborne, Cynthia (NIH) [C] [b6 Simpson, Shelly (NIH) [C]
[b6]; Vogel, Susan (NIH/NIAID) [E] b6]; Grace, Beth (NIH/NIAID) [C]
[b6 Proffitt, Calvin (NIH) [C] b6]; Hohn, Matt (NIH) [C]
[b6 Pierson, Jerome (NIH/NIAID) [C] [b6]; Mock,
Rebecca (NIH/NIAID) [E] [b6]; Segal Ra m, Sharon (NIH) [E] [sharon b6 Mil er,
Tracey (NIH) [C] [b6 Parrish, David (NIH/NIAID) [E] [b6 Galcik, Michael
(NIH) [C] b6]; Dighero-Kemp, Bonnie (NIH/NIAID) [C] [b6]; Hensley,
Lisa (NIH/NIAID) [E] b6 Chen, Helen Q. [b6 Eileen Denning
[b6 Baseler, Beth (NIH) [C] [bbaseler@mail.nih.gov]; Norman Gerry
[b6 DuChene, Alain [b6 Gary Collins [b6 Marie
Hoover [b6 DeBoisblanc, Bennett [b6 Kays, Kyle Richard
[b6 rd.edu]; Huebinger, Ryan M [b6 Elsaid, Olivia
[b6 Dorthe Sandbæk Høgsberg [b6 Hayes,Sharon R.
R.N. (BIDMC - Emergency Medicine) [b6 Park, Pauline [b6 Bryce
Robinson [b6 Katja Bergenholtz b6 Jenny Wilson
[b6 Nadine DuChateau [b6 Rebekah Garcia
[b6 Andrew Vekstein [b6 John Franzone
[b6 Gottlieb, Robert L [b6 Sandkovsky, Uriel S
[b6]; Thomas Holland, M.D. [b6]; Rahul Nair
[b6 Bowdish, Michael [b6 Eyad Almasri
[b6 Sher, Linda [Linda. b6 Scott, James RN [b6
Robinson, Caitlin [b6 Cohen, Mitchell MD [b6 Dr Tatyana Der
[b6 Davey, Richard (NIH/NIAID) [E] [b6 Van, John Nguyen

[b6	Hines-Munson, Casey Eileen [b6	Di Ion, Laura M. (HOU)
[b6	Laurie Spiess [b6	Katja Lisa Kanne [b6
Dawn Hawkins East [b6	Henrik Nielsen [b6	Tomas Østergaard Jensen
[tomas.oestergaard b6	Thomas Lars Benfield [b6	Birgit Thorup
Røge [b6	Sebastian Leicht Von Huth [b6	RH-FP-Epi-
Demus [b6	Huyen Cao [b6	Kinzel, Emily
[Em b6	Berryman, Emily [b6	Emily Ko [b6
Helweg-Larsen [b6	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange	Jannik
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];		
Deconcini, Miranda [b6	Barbara F. McCrum [b6	Holley, H. Preston (NIH)
[C] [b6	Jankelevich, Shirley (NIH) [C] [b6	Jessica Meisner
[b6	Satish Mocherla [b6	Hudock, Kristin
[b6	Carlos O Garner - Lilly b6	Robart, Emily
[b6	Calfee, Carolyn [b6	Exline, Matthew C
[b6	Cate Carey [b6	Holland, Amy [b6
Douglas, Ivor S MD [b6	Hendey, Gregory [b6	Kristine Toft Petersen
[b6	Mette Løkke [b6	

Subject: Standing ACTIV-3 Site Investigators Meeting
Attachments: Talking points for tomorrow morning's ACTIV-3 investigator call
Location: <https://fnih.zoom>. b6

Start: 9/2/2020 2:00:00 PM
End: 9/2/2020 3:00:00 PM
Show Time As: Busy

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: Kirchoff, Matthew (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Mamta Jain; Jens Lundgren; Neaton, Jim; Harrigan, Rachel (HHS/IOS); Higgs, Elizabeth (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E]; Samuel Brown;

b6	b6	b6	Harrington, Cristin A.; Kan, Virginia;
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Biswas, Kousick; Victoria Davey; Baracco Lira, Gio J (Miami VA); Baracco, Gio J, M.D.; Lichtenberger, Paola N. (Miami VA); Bhattacharya, Debika; Krah, Scott E.; Lim, Kokkeang, Williams, Allison E.; Ratliff, Whitney A.; Buck, Theresa A.; Taylor Thompson; b6 Baker, Jason; Catherine Hough; Judith Anne Gallagher; Katharina Krapp, Daniel Dawson Murray, Sueiro, Melyssa (Miami VA); Peter Smith, M.D. (Thoracic Surgery); Christina Chang; Mark Polizzotto; Parker, CAPT Sheri (HHS/IOS); Christine Wenner; ID-Markowitz, Norman, Gardner, Edward M MD; Sanchez, Adriana; Kent P Hassett; Lilian Gonzalez, Andrew G Koustenis; Janice Evans; Wentworth, Debby; b6 Ajay Nirula - Lilly;

b6	Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips; b6
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Birgit Grund (b6 Lane, Cliff (NIH/NIAID) [E]; b6 b6 b6

Emi b6	Eric Hughes; b6	b6 b6 b6
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Judy Currier; b6 Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA); Miller, Marissa A (NIH/NHLBI) [E]; b6 b6 Proschan, Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly, Cavan, Reilly, Roger Paredes, Read, Sarah (NIH/NIAID) [E]; Shweta Sharma, b6 b6 Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria (b6 Aileen I ana, Charles T Benson; Robert Jan Benschop; Lei Shen; Jenny Y Chien; Emmanuel Chigutsa, Daniel A Peterson; Daisy G Hartman; Jamie L Stack; Kristina Southern Dinkel; Susan R Moriarty; Gourab Datta; Patricia L Brown-Augsburger; Denning, Eileen; Larson, Gregg; John Ruie; Teitelbaum, Marc (NIH) [C]; Cahill, Kelly (NIH/NIAID) [E]; Mack, Michael J; Moquete, Ellen; Marks, Mary; Gupta, Lopa; O'sullivan, Karen; Vallee, David; Birgit Grund; b6 b6 b6

b6	b6	b6	b6
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b6	b6	b6	b6

Adam; b6 b6 b6 b6 Badrock, Jonathan; Gregory, Fenton, Kathleen (NIH/NHLBI) [E]; Tadder-Peters, Wendy (NIH/NHLBI) [E]; Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]

Optional Attendees: Carlos O Garner - Lilly; Driver, Brian; Accardi, Evan; Prekker, Matthew; Mackedanz, Shari; Gonzalez, Luis A. (Miami VA); Washburn, Katrina B. (Miami VA); Ramos, Carol F. (Miami VA); Kathleen Lane, RN, BSN; Beth Hollister, Vidaies, Elizabeth; Alyssa Hughes; Sturgill, Jamie; Beverly, Jennifer; Moss, Marc; Rebekah K. Peacock; Mehkri, Omar; Jenna Davis; Chang, Steven Y.; Valerie Aston; Gray, Christopher S, Roth, Megan; Dudley, Adam; Robart, Emily; Nick Johnson; Calfee, Carolyn; Romaine, Connie; Liu, Kathleen Dori; Sarah A Sterling; Jarrod Mosier; Rosseto, Elinita (BIDMC - Emergency Medicine); Hyzy, Robert (Bob); Rice, Todd; D. Clark Files; Duggal, Abhijit; Doernberg, Sarah; DiFiore, Sara; Parry, Blair Alden; Thomas Mazzocco; Utsav Nandi; Agarwal, Trisha; Talmor, Danie S (HMFP - Anesthesia); Higgins, Carrie; Dugar, Siddharth; Kozikowski, Lori-Ann; Bienstock, Karen (NIH/NHLBI) [E]; Akram Khan; Christine A. Lord; Sahoo, Debasis; Jens Ulrik Stæhr Jensen; Steingrub, Jay; De Souza, Lesley; Sandi, Marie; Exline, Matthew C, **b6** Lisbeth Jørgensen; Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014; Tierney, John (NIH/NIAID) [E], Marie Helleberg; Cate Carey; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard; Charlotte Bjernved Nielsen; Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; MacDonald, Leah (NIH) [C]; Ganapathy Gopalrathnam; Janelle A Sabo; Tonya L Combs; Lori J Stephens; Lau, Chuen-Yen (NIH/NIAID) [E]; Herpin, Betsey (NIH/NIAID) [E]; Barrett, Kevin (NIH/NIAID) [E]; Smolskis, Mary (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Osborne, Cynthia (NIH) [C]; Simpson, Shelly (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C]; Proffitt, Calvin (NIH) [C]; Hohn, Matt (NIH) [C]; **b6** Pierson, Jerome (NIH/NIAID) [C]; Mock, Rebecca (NIH/NIAID) [E]; Segal Raim, Sharon (NIH) [E]; Miller, Tracey (NIH) [C]; Parrish, David (NIH/NIAID) [E]; Galcik, Michael (NIH) [C]; Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]; Chen, Helen Q.; Eileen Dening; Baseler, Beth (NIH) [C]; Norman Gerry; DuChene, Alain; Gary Collins; Marie Hoover; DeBoisblanc, Bennett; Kays, Kyle Richard; Huebinger, Ryan M; David Lye Chien Boon (NCID); Elsaid, Olivia; Dortne Sandbæk Høgsberg; Hayes, Sharon R. R.N. (BIDMC - Emergency Medicine); Park, Pauline; Bryce Robinson; Katja Bergenholtz; Jenny Wilson; Nadine DuChateau; Rebekah Garcia; Andrew Vekstein; John Franzone; Gottlieb, Robert L; Sandkovsky, Uriel S, Thomas Holland, M D.; Holland, Amy; Rahul Nair; Bowdish, Michael; Eyad Almasri; Sher, Linda; Scott, James RN; Robinson, Caitlin; Douglas, Ivor S MD; Cohen, Mitchell MD; Dr Tatyana Der; Davey, Richard (NIH/NIAID) [E]; Van, John Nguyen; Hines-Munson, Casey Eileen; Dillon, Laura M. (HOU); Laurie Spess; Hendey, Gregory; Katja Lisa Kanne; Dawn Hawkins East; Henrik Nielsen; Tomas Østergaard Jensen; Thomas Lars Benfield; Kristine Toft Petersen, Birgit Thorup Røge, Sebastian Leicht Von Huth; Mette Løkke; RH-FP-Epi-Demus, Huyen Cao, Kinzel, Emily; Berryman, Emily; Emily Ko; Jannik Helweg-Larsen; Parker, Ashley (NIH/OD) [E]; Deconcini, Miranda; Kirchoff, Matthew (NIH/NIAID) [E]; Barbara F. McCrum; Holley, H. Preston (NIH) [C]; Jankelevich, Shirley (NIH) [C]; Jessica Meisner; Satish Mocherla

Dear All,

Please see the agenda for tomorrow's call. Please note that the NIH Director, Dr. Francis Collins, will be joining us for the first part of the meeting to discuss the importance of the trial and any assistance that the ACTIV team may need to offer.

- Welcome – Jens Lundgren
- Plenary talk by Dr. Francis Collins, NIH director – 10 min
- Needs assessment – Jim, Ginny, Vicky, Taylor & Annetine, – 5 min
- Status of study progress incl feedback from DSMB + goals for September – 15 min
- Update from recruiting sites – brief update from each site (no slides) - 20 min - Uriel (BCW), Peter (Duke), Michael (UCSF), Michael (USC), Clark (Wake), Wesley (Vanderbilt), Bradley (Emory)
- Reporting of SAE/UP without symptoms – 5 min - Marc Teitelbaum, DCR, NIAID
- Release of second newsletter edition + follow-up re discussion on CP – 5 min JL and Sam Brown

Feel free to circulate this invitation to staff at sites that are dedicated to being engaged in ACTIV-3.

Thanks,
Stacey

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+ **b6** US (Tacoma)

Meeting ID: **b6**

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/1/2020 9:03:59 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: Talking points for tomorrow morning's ACTIV-3 investigator call

Francis:

Here are the key themes for your meeting with the ACTIV-3 site investigators. They were agreed between Stacey Adam and Libby Higgs of NIAID:

- NIH, ACTIV, and OWS leadership are very supportive of the trial and the sites conducting it and want to ensure proper resources for trial conduct
- We understand there are challenges being faced to recruitment in the current pandemic
- Sites should think about how ACTIV could help them to ensure smooth stand up of the ACTIV-3 trial
- Importance of prioritizing ACTIV trials (trials are powered for results, benefit from careful design by many experts, carefully prioritized agents etc.)

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/7/2020 12:57:18 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [b6] Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6] Rose Li Central Account [b6] Dana Carluccio [b6] Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [b6] Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencuoc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6] Hargan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]; Nasr, Hana [b6]
Subject: ACTIV-2/-3 Trial Oversight Committee Meeting

Attachments. Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; ACTIV-2/-3 Trial Oversight Committee Meeting; ACTIV-2/-3 Trial Oversight Committee Meeting, Canceled; ACTIV-2/-3 Trial Oversight Committee Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Converting to Ad Hoc: ACTIV-2/-3 Trial Oversight Committee Meeting; Untitled Attachment, Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Ad Hoc ACTIV-2/-3 Trial Oversight Committee Meeting with ASC Members

Location: <https://fnih.zoom.us/> b6

Start: 7/8/2020 7:00:00 PM

End: 7/8/2020 8:00:00 PM

Show Time As: Busy

Recurrence: Weekly

Occurs every Wednesday from 3:00 PM to 4:00 PM effective 7/8/2020 until 12/30/2020.

Required Attendees: Adam, Stacey (FNIH) [T]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier, Davey Smith; Kim, Peter (NIH/NIAID) [E]; b6 b6 Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Centra Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS), Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana

Dear ACTIV-2/-3 TOC Members,

Thank you to all those who weighed in for our recurring meeting time. We will begin meeting from 3-4pm ET on Wednesdays starting July 8th.

Thanks,
Stacey

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To: Goff, David (NIH/NHLBI) [E] [/o=NIH/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=goffdc00]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Bozette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozettesaa]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbac44a1a53dde4e9816f51d-DaveySmith]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Harrigan, Rachel (HHS/IOS)

CC: [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr], Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Sorosa, Alex David [b6 Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Jabarkhail, Mina [b6 Leyva, Jessica M. (Infectious Diseases) [b6 Chen, Helen Q. [b6 Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6 Rose Li Central Account [b6 Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dana Carluccio [b6 Elsaid, Olivia [b6 Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Ginny Kan [b6]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20200819.pdf

Start: 8/19/2020 7:00:00 PM
End: 8/19/2020 8:00:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Smith, David, Kim, Peter (NIH/NIAID) [E]; [b6 [b6 Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Harrigan, Rachel (HHS/IOS); Erhardt, William (HHS/IOS)

Optional Attendees: Leyva, Jessica M. (Infectious Diseases); Chen, Helen Q.; Wholley, David (FNIH) [T]; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Collins, Francis (NIH/OD) [E]; Dana Carluccio; Elsaid, Olivia; Church, Elizabeth (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Victoria Davey; Ginny Kan

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for today's meeting. We will be focusing mainly on discussing recruitment challenges for the trials. This will occur at the start of the meeting.

Thanks,

Stacey

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kiley]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [b6 Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea
 (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Church, Elizabeth
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Erhardt, William
 (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Kelly Beazley
 [b6 Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e];
 Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C]
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 [b6 Dana Carluccio [b6 Church, Elizabeth (NIH/NIAID)
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David
 [b6 Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina
 [b6

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201007.pdf; Lilly BLAZE Combo Data 10072020.pdf

Start: 10/7/2020 7:00:00 PM
End: 10/7/2020 8:00:00 PM

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currer; Smith, David; Kim, Peter (NIH/NIAID) [E]; b6 b6 Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Kelly Beazley; Harrigan, Rachel (HHS/IOS); Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for our meeting today and the slides from the Lilly press conference earlier today for everyone's reference as well, since we will be discussing.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire **b6**; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2], **b6**; **b6** Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

CC: Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]; Chen, Helen Q. [**b6** Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [**b6** .edu]; Lisbeth Jørgensen [**b6** Rose Li Central Account [**b6** Dana Carluccio [**b6** Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [**b6** Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [**b6** Daisy G Hartman [**b6**

Start: 10/14/2020 7:00:00 PM
End: 10/14/2020 8:00:00 PM

Recurrence: (none)

Required Attendees: Erbeling, Emily (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Olmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6** **b6** Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Harrigan, Rachel (HHS/IOS); Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Re ch, Colleen; Lisbeth Jørgensen; Rose Li Central Account, Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkha l, Mina; Daisy G Hartman

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire **b6**; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2], **b6** **b6** Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

CC: Chen, Helen Q. [**b6** Sorosa, Alex David [**b6** Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [**b6** Lisbeth Jørgensen [**b6** Rose Li Central Account [**b6** Dana Carluccio [**b6** Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86], Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [**b6** Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr], Kelly Beazley **b6**

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201023.pdf

Start: 10/23/2020 2:00:00 PM
End: 10/23/2020 3:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Required Attendees: Woodcock, Janet (FDA/CDER); Wholley, David (FNIH) [T]; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (N.H/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Carrier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6** **b6** Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (N H/NHLBI) [E]
Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose J. Centra Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Kelly Beazley

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for today's call.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/19/2020 1:55:25 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; **b6**
Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kiley]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Erica Ollmann Saphire [**b6** Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; **b6** ;
Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]
CC: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Leyva, Jessica M. [Infectious Diseases] [**b6** Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account [**b6** Dana Carluccio [dana. **b6** Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Reich, Colleen

[b6]; Lisbeth Jørgensen [b6 Jabarkhail, Mina
[b6 .edu]; Sorosa, Alex David [b6

Subject: ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20200826.pdf
Location: <https://fnih.zoom.us/j/> b6

Start: 8/26/2020 9:00:00 PM
End: 8/26/2020 10:00:00 PM
Show Time As: Busy

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM
Required Attendees: Marks, Gilbert (OS/ASPR/BARDA) (CTR); Stein, Peter (FDA/CDER); Davey Smith; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Higgs, Elizabeth (NIH/NIAID) [E]; Erbe,ding, Emily (NIH/NIAID) [E]; b6 Kiley, James (NIH/NHLBI) [E]; Kim, Peter (NIH/NIAID) [E]; Erica Ollmann Saphire; Lane, Cliff (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Goff, David (NIH/NHLBI) [E]; Judy Currier; Read, Sarah (NIH/NIAID) [E]; b6 Eakin, Ann (NIH/NIAID) [E]
Optional Attendees: Bugin, Kevin (FDA/CDER); Erhardt, William (HHS/IOS); Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Leyva, Jessica M. [Infectious Diseases]; Harrigan, Rachel (HHS/IOS); Carver, Treia (N-H) [C]; Melencio, Cheryl (FNIH) [T]; Chen, Helen Q.; Elsaid, Olivia; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Reich, Colleen; Lisbeth Jørgensen; Jabarkhail, Mina

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for today's meeting. Please let me know if you have any additions for discussion.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/19/2020 1:55:30 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a313743bbce161547a82f2de-clane]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; **b6**; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Erica Ollmann Saphire [**b6** Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; **b6**
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Reich, Colleen [**b6** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Dana Carluccio [**b6** Leyva, Jessica M. (Infectious Diseases) [**b6** Rose Li Central Account [**b6** Lisbeth Jørgensen [**b6** Jabarkhail, Mina [**b6** Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86];

Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stansellieh}, Elsaid, Olivia
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd};
 Sorosa, Alex David [b6

Subject: ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20200715.pdf
Location: <https://fnih.zoom.us/j/>, b6

Start: 7/15/2020 9:00:00 PM
End: 7/15/2020 10:00:00 PM
Show Time As: Busy

Recurrence: Weekly
every Wednesday from 3:00 PM to 4:00 PM
Required Attendees: Wholley, David (FNIH) [T]; Davey Smith; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Lane, Cliff (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Kim, Peter (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Read, Sarah (NIH/NIAID) [E]; b6 Goff, David (NIH/NHLBI) [E]; Erbelding, Emily (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Marks, Gilbert (OS/ASPR/BARDA) (CTR), Erica Ollmann Saphire; Eakin, Ann (NIH/NIAID) [E]; Judy Currier; b6
Optional Attendees: Wholley, David (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Harrigan, Rachel (HHS/IOS); Bugin, Kevin (FDA/CDER); Reich, Colleen; Melencio, Cheryl (FNIH) [T]; Erhardt, William (HHS/IOS); Carver, Trea (NIH) [C]; Teyhen, Deydre (HHS/IOS); Chen, Helen Q.; Dana Carluccio; Leyva, Jessica M. [Infectious Diseases]; Rose Li Central Account; Lisbeth Jørgensen; Jabarkhail, Mina; Sorosa, Alex David; Church, Elizabeth (NIH/NIAID) [E]; Elsaid, Olivia

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for tonight's meeting.

Thanks,
Stacey

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To: Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Wholley, David (FN H) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Ste n, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Wholley, David (FN H) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6 Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kiley]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [b6 Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea
 (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Church, Elizabeth
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David
 [b6 Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Harrigan, Rache
 (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]; Chen, Helen Q.
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e];
 Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen
 [b6 Lisbeth Jørgensen [b6 Rose Li Central Account
 [b6 Dana Carluccio [b6 Church, Elizabeth (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86];
 Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jabarkhair, Mina
 [b6 Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]

Subject: Canceled: ACTIV-2/-3 Trial Oversight Committee Meeting

Start: 11/11/2020 8:00:00 PM

End: 11/11/2020 9:00:00 PM

Show Time As: Free

Recurrence: (none)

Required Attendees: Stein, Peter (FDA/CDER); Erbeling, Emily (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; b6 b6 Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Dear ACTIV-2/-3 TOC Members,

After speaking with the co chairs, since we have an ad hoc meeting earlier in the day for ACTIV 2 with Lilly and Cliff let me know there are no pressing issues for ACTIV 3, we have decided to cancel this meeting for today to allow many of you a bit more of your holiday back.

Thank you to all our Veterans! And thank you to all of you for all your hard work!

Thanks,
Stacey

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b6

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire **b6**; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2], **b6** **b6** Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]

CC: Chen, Helen Q. [**b6** Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Reich, Colleen **b6** Lisbeth Jørgensen **b6** Rose Li Central Account [**b6** Dana Carluccio [**b6** Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [**b6** Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [**b6** .edu]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201028.pdf

Start: 10/28/2020 7:00:00 PM

End: 10/28/2020 8:00:00 PM

Recurrence: (none)

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ol mann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6** **b6** Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Dear ACTIV-2/-3 TOC Members,

Please see attached the slides for today's call.

Thanks,
Stacey

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To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Higgs, Elizabeth (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Higgs, Elizabeth (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; **b6**
b6 Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kiley]; Goff, David (NIH/NHLBI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [**b6** Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea
(NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Church, Elizabeth
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David
[**b6** Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Harrigan, Rache
(HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]; Bethany Stokes
[**b6** Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda];
Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen
[**b6** Lisbeth Jørgensen **b6** ; Rose Li Central Account
[**b6** Dana Carluccio [**b6** Church, Elizabeth (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86];
Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina
[**b6** Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201104.pdf; SOP for Communications about Significant Updates from ACTIV 11042020v3.docx

Start: 11/4/2020 8:00:00 PM
End: 11/4/2020 9:00:00 PM

Recurrence: (none)

Required Attendees: Higgs, Elizabeth (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6** **b6** Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Bethany Stokes, Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen, Lisbeth Jørgensen; Rose Li Central Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS)

Dear ACTIV-2/-3 TOC Members,

Please find the materials for the for today's meeting.

Thanks,
Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire **b6**; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2], **b6** **b6** Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]

CC: Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Chen, Helen Q. [**b6** Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [**b6** .edu]; Lisbeth Jørgensen [**b6** Rose Li Central Account [**b6** Dana Carluccio [**b6** Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stansellch]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [**b6** Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [**b6** Harngan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201117.pdf

Start: 11/18/2020 8:00:00 PM
End: 11/18/2020 9:00:00 PM

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (N H/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6** **b6** Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (N H/NHLBI) [E]

Optional Attendees: Harrigan, Rachel (HHS/IOS); Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Re ch Colleen; Lisbeth Jørgensen; Rose Li Central Account, Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhal, Mina

Dear ACTIV-2/-3 TOC Members,

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Stacey

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Erica Ollmann Saphire [b6 Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert Mar]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; b6 Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]

CC: Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]; Sorosa, Alex David [b6 Rose Li Central Account [b6 Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Nasr, Hana [b6 Jabarkhail, Mina [b6 Joe Eron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0be0452de96e48b7bc0cbcf5b8d961c-joseph_eron]; Dana Carluccio [dana. b6 Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Reich, Colleen [cjreich@health.ucsd.edu]; Lisbeth Jørgensen [b6 Chen, Helen Q. [b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1f30220cd2d612-William Erh]; Austin Van Grack b6

Location: <https://fnih.zoom>. b6

End: 11/25/2020 9:00:00 PM

Required Attendees: Erica Ollmann Saphire; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Judy Currier; Davey Smith, Goff, David (NIH/NHLBI) [E]; Wholley, David (FNIH) [T]; Erbeling, Emily (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Bozzette, Sam (NIH/NCATS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Javan, Arzhang (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Stein, Peter (FDA/CDER); Kim, Peter (NIH/NIAID) [E]

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire **b6**; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2], **b6**; **b6** Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]

CC: Chen, Helen Q. [**b6** Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda], Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [**b6** Lisbeth Jørgensen [**b6** Rose Li Central Account [**b6** Dana Carluccio [**b6** Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [**b6** Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhal, Mina [**b6** .edu]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel Harr]; Nasr, Hana [**b6** Samuel Brown [**b6** Samuel Brown [**b6**

Start: 12/2/2020 8:00:00 PM
End: 12/2/2020 9:00:00 PM

Recurrence: (none)

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose J Centra Account, Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS), Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; Samuel Brown; Samuel Brown

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6] Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar];

CC: Chen, Helen Q. [b6] Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Reich, Colleen [b6] ; Lisbeth Jørgensen [lisbeth. [b6] Rose Li Central Account [b6] Dana Carluccio [dana. [b6] Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [b6] Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6] Harngan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [b6] Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr];

Attachments: ACTIV-2 and ACTIV-3 Trial Oversight Committee Meeting_20201209.pdf

Start: 12/9/2020 8:00:00 PM
End: 12/9/2020 9:00:00 PM

Recurrence: (none)

Required Attendees: Higgs, Elizabeth (NIH/NIAID) [E]; Wholley, David (FNIH) [T], Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6** **b6** Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

NOTES:

Dear ACTIV-2/-3 TOC Members,

Please find attached the slides for today's meeting.

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Stacey

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To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbba44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbba44a1a53dde4e9816f51d-DaveySmith], Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd], Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [b6 Lisbeth Jørgensen [b6 Rose LJ Central Account
 [b6 Dana Carluccio [b6 Church, Elizabeth (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [b6 Nasr, Hana [b6 Hayden, Frederick G (fgh) [b6
 Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Tressler, Randall
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerf]; Koup, Richard (NIH/VRC)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=86e5e2580a6a44c6a2611fd510de6c96-njsu I]; David Montefiori, Ph.D.
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Gregory Sempowski
 [b6

Subject: Ad Hoc ACTIV-2/-3 Trial Oversight Committee Meeting with ASC Members

Start: 12/16/2020 8:00:00 PM

End: 12/16/2020 9:00:00 PM

Recurrence: (none)

Required Attendees: Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Bozzette, Sam (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Erica Ollmann Saphire; Stein, Peter (FDA/CDER); Judy Currier; Davey Smith; Kim, Peter (NIH/NIAID) [E]; **b6** **b6** Higgs, Elizabeth (NIH/NIAID) [E]; Kiley, James (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Bugin, Kevin (FDA/CDER); Carver, Trea (NIH) [C]; Reich, Colleen; Lisbeth Jørgensen; Rose Li Centra Account; Dana Carluccio; Church, Elizabeth (NIH/NIAID) [E]; Teyhen, Deydre (HHS/IOS); Sorosa, Alex David; Erhardt, William (HHS/IOS); Melencio, Cheryl (FNIH) [T]; Parker, Ashley (NIH/OD) [E]; Jabarkhail, Mina; Harrigan, Rachel (HHS/IOS); Nasr, Hana; Hayden, Frederick G (fgh); Gregory Sempowski; Marovich, Mary (NIH/NIAID) [E]; Tressler, Randall (NIH/NIAID) [E]; Koup, Richard (NIH/VRC) [E]; Sullivan, Nancy (NIH/VRC) [E]; David Montefiori, Ph.D.; Aggarwal, Neil (NIH/NHLBI) [E]

Dear ACTIV-2/-3 TOC Members,

As noted by the change in the title of the meeting, we will be changing this TOC meeting to an Ad Hoc TOC to allow for the attendance of the ASC members for the discussion of the independent testing data and their suggestions for its use.

This discussion will take place after our usual general trial updates.

Thanks,
Stacey

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+	b6	US (Tacoma)

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]
Sent: 5/4/2020 3:56:47 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [b6] Anderson, Margaret [b6] Gonzalez, Nina [b6] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [b6] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [b6] Tolman, Brett [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Elsaid, Olivia [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]
Subject: Pre-call for ACTIV Executive Committee Call
Attachments: FW: ACTIV Executive Committee Meeting 202005017dw pptx
Location: see webex below
Start: 5/18/2020 2:30:00 PM
End: 5/18/2020 3:00:00 PM
Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Elsaid, Olivia; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Optional Attendees: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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From: Cutillo, Christine (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C04C8F5063C34361BB7491F216F75ADC-CUTILLOC]
Sent: 6/4/2020 2:10:41 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Rashid, Kamilah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce52e57bb74034834aa8660b5c8677-rashidkl]; Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2bf13-walsher]
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

I'm not sure I understand what you mean by a few of your questions and comments. I think there is some misunderstanding about items. Would you be available sometime this morning to discuss? I can be available anytime before 12p.

What training and portal are you referring to? We have supported a few different ones, so your help on clarifying this will enable me to understand your questions better.

For items received through the OD portal – Deloitte/ACTIV has been planning on tracking the status of those that ACTIV receives, not however any of the items that are sent to RADx nor the ICs since it's not in their remit.

For the ACTIV compounds survey – this is just about to go out (it sounded like the emails were being finalized yesterday) and we starting discussing with the FNIH/Deloitte ACTIV teams about the process/procedure once they receive new compound suggestions from the OD portal (e.g., likely would need to be prioritized and then trigger the ACTIV compounds survey being sent). It sounds like this still needs to be determined, but Nina/Ben/Dina have it on their radar as an item to tackle next. The thing that Deloitte first needs to hash out is the data flow/schematic so that we can appropriately determine all the processes and procedures.

Best,
Christine

Christine Cutillo, MMCI
Special Assistant to the Director
Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health
b6

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Parker, Ashley (NIH/OD) [E] <b6>
Sent: Wednesday, June 3, 2020 7:42 PM
To: Cutillo, Christine (NIH/NCATS) [E] <b6>
Cc: Austin, Christopher (NIH/NCATS) [E] <b6> Rashid, Kamilah (NIH/OD) [E]
<b6> Walsh, Elizabeth (NIH/OD) [E] <b6>
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

As promised, please see the attached agents received by the COVID-19 portal May 23-May 29 and were selected by the NIH SMEs to move forward for ACTIV. 54 submissions were received in total.

NIH OD (Kamilah and Beth from Tara's team and myself) have a training scheduled tomorrow to learn more about the dashboard NCATS has funded. I still haven't quite yet wrapped my head around how all these things will be tracked. Francis is interested in knowing how we will be able to track all compounds that come in to the COVID-19 portal that is then shared with RADx, ACTIV, ICs, etc. – what happens to all of them if asked what happened with compound X? I assume this is the million dollar project.

I'm also aware if the 2nd tier portal/survey ACTIV and NCATS has developed for additional information but still not clear on how this will be handled for logistical/process purposes.

Christine – it would be useful if we could chat for 15-30 mins this week to touch base and discuss. Please let me know if your schedule allows.

Thank you,
Ashley

From: Austin, Christopher (NIH/NCATS) [E] **b6**
Sent: Monday, June 1, 2020 8:57 AM
To: Parker, Ashley (NIH/OD) [E] **b6**; Cutillo, Christine (NIH/NCATS) [E] **b6**
Cc: Adam, Stacey (FNIH) [T] **b6**; Ford-Scheimer, Stephanie (NIH/NCATS) [C] **b6**
>; Rashid, Kamilah (NIH/OD) [E] < **b6**
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

Many thanks – this is just what we need and will be very useful for ensuring that our inventory process is comprehensive. In addition, the way the data are presented is quite good and will help us in our efforts to determine how to do that broadly.

All best,

Chris

From: Parker, Ashley (NIH/OD) [E] < **b6**
Sent: Sunday, May 31, 2020 8:48 PM
To: Austin, Christopher (NIH/NCATS) [E] **b6**; Cutillo, Christine (NIH/NCATS) [E] **b6**
Cc: Adam, Stacey (FNIH) [T] **b6**; Ford-Scheimer, Stephanie (NIH/NCATS) [C] **b6**
Rashid, Kamilah (NIH/OD) [E] **b6**
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Chris and Christine,

Got it! Attached is the spreadsheet of emails received between early March and late May. With the NIH COVID 19 Candidates and Technologies Portal now live, all emails relevant to ACTIV are being routed there for submission and we've only had one round of review by the NIH COVID portal review group for inquiries received May 14-22 – please see

2nd attachment. The review group received a total of 58 submissions, 15 were determined to have potential – 8 of which are relevant to ACTIV.

Christine – I will cc you when we receive these each week. The 2nd attachment will provided an idea of the data fields used for the COVID portal.

We are still working on a process for receiving candidates from BARDA that have been reviewed by NIH staff who attend the BARDA held CoronaWatch meetings. Hopefully we can easily integrate those into a single spreadsheet to be shared. I've been working closely with Kamilah on Tara's team with this and we've discussed some of the questions outlined below –cc'ing Kamilah in case she has anything to add

Thanks,
Ashley

From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Sunday, May 31, 2020 11:18 AM
To: Parker, Ashley (NIH/OD) [E] b6
Cc: Cutillo, Christine (NIH/NCATS) [E] b6 Adam, Stacey (FNIH) [T] < b6 Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Ashley,

Thank you for all your efforts and sorry for the delay in getting back to you; as you know, ACTIV has been busy!

Just want to clarify the portals issue. You're right that Larry has brought Deloitte in to do a larger assessment of COVID informatics needs since many ICs have asked for solutions; he and Susan G are leading that and there is a WG of us ICDs that will help. The immediate portal need is for ACTIV, to allow their prioritization teams, coordinated by Joe Menetski and Stacey Adam at FNIH, to have all the possible assays and agents to consider for inclusion. Christine Cutillo is working very closely with the FNIH and Deloitte teams to bring all the entries from many different portals into a single database. We want to be sure to include the entries that the OD portal is getting.

If you are sending all the submissions from the OD portal to FNIH already, the issue may have been solved indirectly already since the combined NIH-FNIH-Deloitte group has the OD entries. But it does appear quite odd for the NIH IC partners on ACTIV (coordinated by Christine Cutillo) to not receive NIH data from the OD, but rather have to get it from FNIH. Hence my request to simply get the information directly from you. To prevent any entries from falling through the cracks, pls begin copying Christine on the information you share with FNIH each week.

Hope this makes sense. Thanks,

Chris

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, May 20, 2020 7:12 PM
To: Cutillo, Christine (NIH/NCATS) [E] < b6 Adam, Stacey (FNIH) [T] < b6 Anderson, James (NIH/OD) [E] b6
Cc: Austin, Christopher (NIH/NCATS) [E] b6 Santangelo, George (NIH/OD) [E] b6 Ford-Scheimer, Stephanie (NIH/NCATS) [C] < b6 Gladman, Jordan (NIH/OD) [E] b6 >
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Christine,

There have been a few updates since the note from Chris on Sunday and I want to clarify a few things.

- We have not received any spreadsheets from BARDA with data fields – one of the NIAID POs who is a reviewer for the BARDA CoronaWatch meetings shared a PDF short list of compounds for ACTIV Tx clinical WG to consider – this is what I shared on Friday.
- The spreadsheet OD has managed prior to the launch of the COIVD portal only contains emails (contact info, brief descriptor i.e. vaccine, preclinical interest, etc.) Dr. Collins has received as it relates to ACTIV. We have shared these with FNIH each week to sort and share relevant information with the WGs. ES has sent a standard response to those emails and in some cases FNIH has followed up when relevant. I think only a handful may have been fully useful and fleshed out.
- Tara's team is leading the NIH portal efforts – yes, data fields are closely aligned with BARDA. Also, Tara's team has a review process for queries received through this portal and would have the spreadsheet of data fields you are looking for – it may be a good idea to touch base with Tara and her team to ensure the efforts outlined below are aligned.
- **As of yesterday, my understanding was Dr. Tabak made a decision to coordinate these efforts via a small IC data group and next steps are to bring in PM from Deloitte as you've indicated below to access all of the needs including RADx, ACTIV, and others before making a final decision to merge information from all portals. My take on this was to pause for the moment but I defer to Chris on the action items below.**

I hope this is useful.

Best,
Ashley

From: Cutillo, Christine (NIH/NCATS) [E] b6
Sent: Wednesday, May 20, 2020 3:37 PM
To: Adam, Stacey (FNIH) [T] b6 >; Parker, Ashley (NIH/OD) [E] < b6 >; Anderson, James (NIH/OD) [E] b6
Cc: Austin, Christopher (NIH/NCATS) [E] b6 . Santangelo, George (NIH/OD) [E] < b6 Ford-Schelmer, Stephanie (NIH/NCATS) [C] b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Dear All,

Wanted to provide you with an update – we have been working with Andrew Derr (Deloitte NIH contract) to get someone by tomorrow/end of the week to start working on this. More detailed steps are included below in addition to a few questions. For clarification – which spreadsheet/database contains the appropriate data fields that should be propagated/mapped for each of the others (e.g., the BARDA submissions or the ACTIV compound spreadsheet)? I believe the NIH portal was built based on the BARDA submission data fields, but if we're ultimately aiming to connect to the ACTIV compound spreadsheet then potentially we should build toward that now when connecting these unsolicited submissions. Also, where do the submissions received via the NIH portal live and/or will a spreadsheet be sent at some periodicity? I apologize if these are questions that have already been addressed, but I haven't received that information yet.

Best,
Christine

1. Merge relevant information from all portals mapped to consistent data fields into the N H db ("relevant" means submissions relevant to the ACTIV process; some NIH portals will contain COVID-related but not ACTIV-relevant entries)
 - a. BARDA submissions – ***is this the template of data fields that all others should be aligned with or should they be aligned with the data fields contained within the ACTIV compound spreadsheet?***
 - b. OD received submissions (prior to implementation of portal) ***Ashely***, do you have this spreadsheet and have the data fields already been aligned with BARDA and/or the NIH portal?
 - c. NIAID submissions – spreadsheet provided by Alan Embry (contact him to ensure on same page); data fields need to be mapped/aligned
 - d. NCATS submissions – data fields need to be mapped/aligned
2. Eliminate duplicate entries (sent by the same person to multiple portals)
 - a. Via name/email matching
3. Send email to those not submitted through the NIH portal
 - a. Permission to integrate into ACTIV prioritization
 - b. Fill out survey – ***either compound RedCap survey or NIH portal depending on answer to initial question – thinking it's the former?***
4. Collate all into single db/spreadsheet for ACTIV/TransNIH use
5. Set up process for updating submissions received via N H portal and other sources
 - a. ***Where do the submissions received via the NIH portal live and/or will a spreadsheet be sent at some periodicity?***
 - b. ***Has an email been sent out alerting folks at NIH to direct external inquiries to this portal or do we need to set up a process for receiving new submissions from e.g., NIAID?***

Christine Cutillo, MMCI
 Special Assistant to the Director
 Office of the Director
 National Center for Advancing Translational Sciences
 National Institutes of Health
 b6

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Sunday, May 17, 2020 12:37 PM
To: Adam, Stacey (FNIH) [T] <b6>, Parker, Ashley (NIH/OD) [E] b6 Cutillo, Christine (NIH/NCATS) [E] b6 Ford-Scheimer, Stephanie (NIH/NCATS) [C] b6
 ; Anderson, James (NIH/OD) [E] b6 >; Santangelo, George (NIH/OD) [E] b6
Subject: FW: BARDA Corona Watch | Therapeutic Candidates for Consideration

All,

We made good headway last week on a strategy to eliminate redundant entries from different submission portals to enable a complete and nonredundant list of entries to be provided to Stacey's group for wave 2 and wave 3 prioritization. The list from BARDA enclosed, and the analysis Stacey did on it, is just the kind of information we have, or need to extract, from the NIAID portal, NCATS portal, Bldg 1 portal, intramural portal, and nonpublic OPA db. The steps defined are:

1. Merge relevant information from all portals into the NIH db ("relevant" means submissions relevant to the ACTIV process; some NIH portals will contain COVID-related but not ACTIV-relevant entries)
2. Eliminate duplicate entries (sent by the same person to multiple portals) by name/email matching

3. Depending on whether the portal required the submitter to grant permission for sharing internal to NIH and/or with ACTIV (latter, non-NIH for evaluation purposes only, under NDA), send submitter an email asking for such permission to be granted, and
4. Depending on whether the submitter included the fields needed by Stacey's group for initial evaluation, in same email ask the submitter to supply the missing information
5. Collate responses and deliver to Stacey.

Christine, please devise a sequential workflow and enlist those you need for help.

Many thanks to all the portal owners for helping to create a filter funnel that will get the relevant information to ACTIV.

Chris

From: Adam, Stacey (FNIH) [T] **b6**
Sent: Saturday, May 16, 2020 11:05 AM
To: Freire, Maria (FNIH) [T] < **b6** >; Collins, Francis (NIH/OD) [E] **b6**
Cc: Parker, Ashley (NIH/OD) [E] < **b6** >; Tabak, Lawrence (NIH/OD) [E] **b6** >;
Lane, Cliff (NIH/NIAID) [E] **b6** >; Austin, Christopher (NIH/NCATS) [E] **b6** >;
Anderson, James (NIH/OD) [E] **b6** >; Wholley, David (FNIH) [T] **b6**
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria,

Of the top three candidates we selected: Abatacept (CTLA-IgG1 Fusion), Cenicriviroc (CCR2/5 inhibitor), and Infliximab (TNF-alpha antagonist). Only the TNF inhibition seems to appear on the BARDA list.

Of our top 39 candidates that got scored, many MOAs were working to address some of the same issues that those on the BARDA list seem to target, such as anticoagulants, though those we reviewed and selected were largely already available in hospitals so they could be easily and quickly deployed for the NHLBI/NINDS trial. BARDA's anticoagulants seem to be next generation and working through slightly different MOAs. Also, we had number of anti-inflammatory targeting MOAs on our list that don't appear on the BARDA list, such as anti-IL17, RASp inhibition, PDE4 inhibition, GSK-3b inhibition, and others. But again, both groups trying to get at the same issue, just through different points in the inflammation pathway. The one thing I notice is the BARDA list only seems to have 1 antiviral on their list, whereas we have about 9, and while we didn't prioritize them first, we did think some would likely be high priority for our next wave of trials with a slightly different design.

Again, I hope this is helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: **b6** Mobile: **b6**

From: Freire, Maria (FNIH) [T] < **b6** >
Sent: Saturday, May 16, 2020 10:51 AM
To: Adam, Stacey (FNIH) [T] < **b6** >; Collins, Francis (NIH/OD) [E] < **b6** >
Cc: Parker, Ashley (NIH/OD) [E] < **b6** >; Tabak, Lawrence (NIH/OD) [E] < **b6** >;
Lane, Cliff (NIH/NIAID) [E] **b6** >; Austin, Christopher (NIH/NCATS) [E] **b6** >

Anderson, James (NIH/OD) [E] b6 >; Wholley, David (FNIH) [T] b6

Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Thank Stacey- very helpful. How about the converse: are there MOA on the WG list that are not on this one? M.

From: "Adam, Stacey (FNIH) [T]" b6
Date: Saturday, May 16, 2020 at 9:40:55 AM
To: "Freire, Maria (FNIH) [T]" b6, "Collins, Francis (NIH/OD) [E]" b6
Cc: "Parker, Ashley (NIH/OD) [E]" <b6> "Tabak, Lawrence (NIH/OD) [E]" b6,
"Lane, Cliff (NIH/NIAID) [E]" <b6> "Austin, Christopher (NIH/NCATS) [E]" b6 >,
"Anderson, James (NIH/OD) [E]" b6 >, "Wholley, David (FNIH) [T]" b6
Subject: RE: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi Maria and Francis,

As these compounds largely did not have information in the public domain for ongoing trials or major preclinical experiments in SARS-CoV-2 when we did our first pull 5 weeks ago, most, if not all, would not have been on our list.

However, looking at the mechanisms of action (MOA), we did have a number of agents that have same or similar MOAs, including IL-6 inhibition (3 agents on our review list) and JAK/STAT inhibitors (4 on our list). Both of these classes our group chose not to select for the first large confirmatory trial we were designing because their MOAs were being studied in well designed trials by other groups.

There are some MOAs that were not on our original list, such as IL-15 inhibition, though we did have many other IL inhibitors, including IL-1, 6, and 17. The Syk inhibitors are also a new MOA that did not appear in the first 170 of clinically ready agents.

I hope this information helps.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct b6 Mobile: b6

From: Freire, Maria (FNIH) [T] b6
Sent: Saturday, May 16, 2020 10:03 AM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Parker, Ashley (NIH/OD) [E] <b6> Tabak, Lawrence (NIH/OD) [E] b6 ;
Lane, Cliff (NIH/NIAID) [E] b6 >; Austin, Christopher (NIH/NCATS) [E] b6 ;
Anderson, James (NIH/OD) [E] b6, Wholley, David (FNIH) [T] <b6> >; Adam,
Stacey (FNIH) [T] b6
Subject: Re: BARDA Corona Watch | Therapeutic Candidates for Consideration

Good morning Stacey. Could you please take a look and let us know? Many thanks, M

On May 16, 2020, at 8:46 AM, Collins, Francis (NIH/OD) [E] b6 > wrote:

Interesting. Would the therapeutics on this list have been on the list of 170 that the Therapeutics Clinical WG was prioritizing?

FC

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Friday, May 15, 2020 2:49 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>; Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>; Anderson, James (NIH/OD) [E] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>; Freire, Maria (FNIH) [T] <[REDACTED]>
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]>
Subject: BARDA Corona Watch | Therapeutic Candidates for Consideration

Hi all,

Attached is a list of compounds shared by one of NIAID's program officers, Steve Smiley who is a reviewer/participant assigned to the **therapeutics Tech Watch (now CoronaWatch) meetings** at BARDA. Steve indicated they have ~10 meetings per week and there are other NIAID experts who join these. He suggested NIH reps who attend the BARDA meetings could assist with sharing compounds with ACTIV – recent focus has been on therapeutic products for infected outpatients for the DAIDS ACTG network but he indicated many products are better suited to phase 2 testing in hospitalized patients.

Steve also suggested we develop a short script for the NIH POCs who attend the BARDA Corona Watch meetings and use this as an opportunity to inform companies about ACTIV. We could link them to our vetting process (i.e. new portal) and/or feed them directly to the working groups. It seems prior to ACTIV, NIAID has used these Corona watch meetings to look for opportunities that would be useful for NIAID networks – Cliff likely has more insight here. The opportunity to expand and be inclusive of ACTIV seems like the right path and an opportunity to stay connected with what comes through BARDA.

Would this be something of interest to the group?

Thanks,
Ashley

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]
Sent: 7/21/2020 6:06:43 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [b6] Anderson, Margaret [b6] Chen, Helen [b6] Elsaid, Olivia [b6] Gonzalez, Nina [b6] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [b6] Tolman, Brett [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Hawk, Harrison [b6]

Subject: ACTIV Leadership Team Pre-call
Attachments: RE: ACTIV Leadership Team Pre-call
Location: see webex below

Start: 8/24/2020 4:00:00 PM
End: 8/24/2020 4:30:00 PM
Show Time As: Busy

Required Attendees: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Hawk, Harrison

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/24/2020 3:46:14 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [b6] Anderson, Margaret [b6] Chen, Helen [b6] Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiyp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [b6]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: RE: ACTIV Leadership Team Pre-call
Attachments: 8.26 ACTIV Leadership Team Meeting 20200824 for review.pptx; Copy of August 26 ACTIV Leadership Team Attendance.xlsx; 2020-08-14_Executive_Committee_Meeting_Summary vFinal.docx

Please see attached materials for our noon ACTIV EC pre-call. Thanks, David

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/4/2020 3:56:16 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [b6 Adam, Stacey (FNIH) [T] [b6 Alvarez, Rosa [b6 Anderson, Margaret [b6 Gonzalez, Nina [b6 James, Stephanie (FNIH) [T] [b6 Kim, Elizabeth [b6 Menetski, Joseph (FNIH) [T] [b6 Santos, Michael (FNIH) [T] [b6 Stratton, Ben [b6 Tolman, Brett [b6 Tountas, Karen (FNIH) [T] [b6 Wachtel, Jonathan [b6 Wholley, David (FNIH) [T] [b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [b6 McManus, Ayanna (NIH/OD) [E] [b6 Elsard, Olivia [b6
Subject: Pre-call for ACTIV Leadership Call #3
Location: see webex below
Start: 5/4/2020 8:00:00 PM
End: 5/4/2020 8:30:00 PM
Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Parker, Ashley (NIH/OD) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Elsard, Olivia

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Tap to call in from a mobile device (attendees only)

b6 Call-in toll number (US/Canada)

Global call-in numbers

Join using Microsoft Lync or Microsoft Skype for Business

Dial b6 go.lync.webex.com

Join the meeting

If you are a host, go here to view host information. IMPOR

From: Alvarez, Rosa Maria [b6]
Sent: 7/21/2020 2:48:32 PM
To: Alvarez, Rosa Maria [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Nancy Haigwood [b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hawk, Harrison [b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]

Subject: ACTIV Preclinical - In vivo Strategy

Attachments: Untitled Attachment; ACTIV Preclinical - In vivo Strategy; ACTIV Preclinical - In vivo Strategy; Canceled: ACTIV Preclinical - In vivo Strategy ; Canceled: ACTIV Preclinical - In vivo Strategy , Canceled: ACTIV Preclinical - In vivo Strategy ; ACTIV Preclinical Working Group Meeting - Scenario Planning Discussion

Location: <https://deloitte.zoom.us/j/91812130000> [b6]

Start: 6/12/2020 2:00:00 PM

End: 6/12/2020 3:00:00 PM

Show Time As: Busy

Recurrence: (none)



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To: Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6] Alvarez, Rosa Maria [b6] Young, John [b6] Hawk, Harrison [b6] Rodriguez, Robin D [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; [b6] [b6] [b6] Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [b6] [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]

Subject: ACTIV Preclinical - In vivo Strategy

Start: 8/7/2020 2:00:00 PM

End: 8/7/2020 3:00:00 PM

Recurrence: (none)



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[b6]

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To: Alvarez, Rosa Maria [b6 Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6 Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [b6 b6 b6 Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6 Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Hawk, Harrison [b6 Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6

Subject: ACTIV Preclinical - In vivo Strategy

Start: 8/14/2020 2:00:00 PM
End: 8/14/2020 3:00:00 PM

Recurrence: (none)

To: Hawk, Harrison [b6 Alvarez, Rosa Maria [b6 b6
Young, John [b6 Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];
Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
b6 b6 Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Pitt, Margaret L
CIV USARMY MEDCOM USAMRIID (USA) [b6 b6 b6
Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D
b6 Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Hawk, Harrison
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory
b6 ; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]

Subject: Canceled: ACTIV Preclinical - In vivo Strategy

Start: 9/4/2020 2:00:00 PM

End: 9/4/2020 3:00:00 PM

Show Time As: Free

Recurrence: (none)

Hi all,

Several of you have noted that you are out of the office today. We will cancel this meeting today and meet again next week.

Hope everyone enjoys the long weekend!

Best regards,

Rosa

Rosa M. Álvarez

Deloitte Consulting LLP

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To: Alvarez, Rosa Maria [b6] Young, John [b6] [b6]
Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; [b6] [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [b6] [b6] [b6]
Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]

Subject: Canceled: ACTIV Preclinical - In vivo Strategy

Attachments: 20200918_ACTIV Preclinical_In Vivo Strategy_Notes_v2.docx

Start: 9/25/2020 2:00:00 PM

End: 9/25/2020 3:00:00 PM

Show Time As: Free

Recurrence: (none)

Hi all,

Please find attached the notes from our last meeting (apologies for the delay).

We will be canceling tomorrow's meeting, but please be on the lookout for an email as we will be following up to our conversation from last week to request that the team to share thoughts on where are the gaps currently in the preclinical space and what can we do to support them through the end of 2020, if ACTIV stays active through the end of 2021 or 2022.

Let us know if you have any questions.

Regards,

Rosa



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Meeting ID:

Password:

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To: Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Alvarez, Rosa Maria [b6]; Young, John [b6]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [rmdaigle@tulane.edu]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]

Subject: Canceled: ACTIV Preclinical - In vivo Strategy

Start: 10/2/2020 2:00:00 PM

End: 10/2/2020 3:00:00 PM

Show Time As: Free

Recurrence: (none)

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Dial:

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Password:

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To: Alvarez, Rosa Maria [b6 Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskip]; Young, John [b6 Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6 Gatto, Gregory [b6 Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; [b6 Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6 ; [b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6 Tomas Cihlar [b6 Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [b6 Punturien, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiena]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Prabhavathi Fernandes [b6 Diamond, Michael [b6 Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; [b6 Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6 Baric, Toni C [b6 Rodriguez, Robin D [b6 Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]

Subject: ACTIV Preclinical Working Group Meeting - Scenano Planning Discussion

Start: 10/9/2020 2:00:00 PM

End: 10/9/2020 3:00:00 PM

Recurrence: (none)

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 12/26/2020 10:54:10 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [[b6 Collins, Francis (NIH/OD) [E] [b6 ; Tabak, Lawrence (NIH/OD) [E] [[b6 Austin, Christopher (NIH/NCATS) [E] [[b6]; Anderson, James (NIH/OD) [E] [[b6 Gibbons, Gary (NIH/NHLBI) [E] [[b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [[b6 Patterson, Amy (NIH/NHLBI) [E] [[b6
CC: Wood, Gretchen (NIH/OD) [E] [[b6 McManus, Ayanna (NIH/OD) [E] [[b6 Simon, Dina (NIH/OD) [C] [[b6 Burrus-Shaw, Cyndi (NIH/OD) [E] [[b6 Lagos, Enrique (NIH/NCATS) [E] [[b6 Sepulveda, Donna (FNIH) [T] [[b6 Hughes, Karen (NIH/OD) [E] [[b6 Dimishkov, Roxanne (NIH/NHLBI) [C] [[b6 Carver, Trea (NIH) [C] [[b6
Subject: ACTIV Call "War Room"
Location: Dial-in: [b6 Passcode: [b6
Start: 12/30/2020 3:30:00 PM
End: 12/30/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Parker, Ashley (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Patterson, Amy (NIH/NHLBI) [E]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Hughes, Karen (NIH/OD) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Carver, Trea (NIH) [C]

Changing to 10:30 a.m. due to conflict on Dr. Collins' calendar.

Dial-in: [b6
Passcode: [b6

Dr. Tabak as Leader: [b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/12/2020 3:54:59 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Attachments: Proposal for ACTIV leadership-vf 051220.pdf

Francis et al.

Regarding the proposal for data sharing and data warehouse in Section III, 4 of the letter we just received; **some news or views regarding the following may come up on tomorrow's call, so I wanted you to be aware:**

I was going to bring this up on this morning's war room call but there was not enough time. I had a call yesterday with Anne Heatherington of Takeda, who has been charged by the COVID-19 R&D Leaders Consortium (which I understand now includes representation from 20 companies) with figuring out their data sharing strategy. I gave her an update on what we have been doing and intend to do (she was quite impressed with the progress on ACTIV), including an overview of our various data inventory/database/tools efforts, which of necessity have been focused on serving our immediate initiatives in therapeutics and vaccines testing. As you can see from the attached PP deck, they have been busy as well, getting commitments from members to share both summary-level and patient level data from clinical trials, and investigating access to real-world data.

While the real-world data piece continues to evolve, Anne said they have reached a pretty firm decision to share study-level trials data via the Gates Tx Accelerator and individual patient level data from their trials via Transcelerate. The latter had a press release a couple of weeks ago saying they would share control arm data among their members first and work toward sharing that beyond their membership. Anne claims that as of Friday, however, the Transcelerate board has decided to move forward to house treatment arm data as well and throw access open to the non-members.

Anne's question is whether and how NIH can join the party. Despite the plethora of small, underpowered IIS studies, there are a number of good RCTs being run by academic sites, most funded by NIH of course. And there is the question of what happens to the data from the trials being advanced through ACTIV. Can NIH/ACTIV find a way to include these data in the nominated repositories?

I realize this is subject to a lot more discussion, but I wanted to mention it now in the event it comes up on tomorrow's EC call. By the way, I asked Anne what exact questions the COVID R&D Consortium leadership hopes to be able to ask of these data and though I am sure there are some, what they are is still apparently a work in process.

David

From: Jonson, Samantha (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE2F69369D654BEF89B0D39B145D69A7-JONSONSG]
Sent: 8/19/2020 5:56:00 PM
To: Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Trans NIH COVID19 Clinical Trial Initiative [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=987964ae93184aeb96b8cad91a86dc2-Trans NIH C]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Nyawara, Junnette (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1c46144f5a24bde8a484f144fff9163-nyawaraja]; Misik, Joseph (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6ea3eb0310547b99262c6566d662672-miskijj]; Bal, Jasjit (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a703c46066c4c4cad33d09edb8ddece-baljk]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Kurlla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]
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(NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: Demo: COVID-19 Clinical Trial Tracker
Attachments: TransNIH 2 WG: Access to COVID-19 Clinical Trial Tracker
Location: WebEx Link Enclosed

Start: 8/20/2020 5:30:00 PM
End: 8/20/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Trans NIH COVID19 Clinical Trial Initiative, Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Nyawara, Junnette (NIH/NCATS) [C]; Misik, Joseph (NIH/NCATS) [C]; Bal, Jasjit (NIH/NCATS) [C]; Dickens, Jim (NIH/NCATS) [C]; Kurilla, Michael (NIH/NCATS) [E]
Optional Attendees: Freire, Maria (FNIH) [T]; Wholey, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Garbarini, Nicole (NIH/NCATS) [E]; Dunsmore, Sarah (NIH/NIGMS) [E]; Schully, Sheri (NIH/OD) [E]; Sizemore, Christine (NIH/FIC) [E]; Boucher, Cynthia (NIH/NCATS) [E]; Sazonova, Irina (NIH/NIA/ERP) [E]; Payton, Man zhe (NIH/NIAID) [E]; Gorospe, J Rafael (NIH/OD) [E]; Bushar, Nicholas (NIH/NIAID) [E]; Sina, Barbara (NIH/FIC) [E]; Weber, Wendy (NIH/NCCIH) [E]; Hall, Janet (NIH/NEHS) [E]; Bhargava, Sangeeta (NIH/NEI) [E]; Kehl, Karen (NIH/NINR) [E]; Massett, Holly (NIH/NIA/ERP) [E]; Mooney, Margaret (NIH/NCI) [E]; Simon, Alan (NIH/OD) [E]; Frost Bellgowan, Julie (NIH/NIDA) [E]; Sheehan, Jerry (NIH/NLM) [E]; Tumminia, Santa (NIH/NEI) [E]; Gillman, Matthew (NIH/OD) [E]; Dahut, William (NIH/NCI) [E]; Bergeris, Annice (NIH/NLM/NCBI) [E]; Yu, Hanna (FNIH) [T]; Brennan, Patti (NIH/NLM) [E]; Subramaniam, Geetha (NIH/NIDA) [E]; Passamani, Eugene (NIH/NCATS) [C]; Aggarwal, Neil (NIH/NHLBI) [E]

Sincere apologies for the number of updated meeting invites today. Due to technical difficulties experienced at NIH yesterday, the WebEx meeting information has been updated.

Hello,

As a member of the **TranNIH2 working group** (see emailed attached) or the **FNIH team involved in ACTIV**, you received an email last week stating that you had access to the **COVID-19 Clinical Trial Tracker (CCTT) dashboard**. If available, please join us for a brief demo of the system. If you are unable to make this time, a recording of this demo will be circulated so you can view it at your convenience.

The CCTT is populated with curated data sent to NIH from the Operation Warp Speed team at the FDA. The curated data gives you access to all the reported COVID-19 clinical trials across the globe using public information from clinicaltrials.gov and the WHO global database.

Please review your log-in instructions ahead of this meeting.

Best,
NCATS

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Join in the meeting

If you are a host, [click here to view host information](#).

From: Alvarez, Rosa Maria [b6]
Sent: 7/21/2020 2:21:28 PM
To: Alvarez, Rosa Maria [b6]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Gatto, Gregory [b6]; Diamond, Michael [b6]; Mason, Stephen [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email], Baric, Toni C [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]
CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]
Subject: Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites
Attachments: ACTIV Preclinical - Network of BSL 3 / 4 sites ; Untitled Attachment; Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites ; ACTIV Preclinical Network - Prioritization of Preclinical-stage agents; Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites ; Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites ; Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites ; Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites ; Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites ; Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites
Start: 6/9/2020 3:00:00 PM
End: 6/9/2020 4:00:00 PM
Show Time As: Free
Recurrence: (none)

Hi all,

We will be canceling meetings for this sub-group and will rejoin as needed. For now, we will be consolidating into the Preclinical Network team that will be doing prioritization as well as support the match-making recommendations.

Best,
Rosa

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To: Alvarez, Rosa Maria [b6 Young, John b6 Diamond, Michael
[b6 Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T]
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Subject: Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites

Start: 8/11/2020 3:00:00 PM

End: 8/11/2020 4:00:00 PM

Show Time As: Free

Recurrence: (none)

Hi all,

Canceling this meeting today as we will be focusing on the Preclinical Agent Prioritization. I will send a meeting invite for early next week to discuss the Match-Making process for the compounds to be prioritized.

Best,

Rosa

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To: Alvarez, Rosa Maria [b6] Diamond, Michael [b6] Young, John [b6]
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras], Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Gatto, Gregory [b6]; Mason, Stephen [b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Baric, Toni C [b6] Kara Carter [b6]
Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Kolykhalov, Alexander A. [b6] Michael Sofia [b6]
Denison, Mark (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39e8760f26024042916d630592b4c15f-mark deniso], Mark Krystal [b6]
Johnson, R. Paul [b6] Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Hawk, Harrison [b6]
Tomas Cihlar [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-naigwoon.oh]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Sumit Chanda [b6]
Challberg, Mark (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28a89f5b6a384b1a864e1ef36d058da7-mchallberg]; Sciotti, Rick (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afc7c6959cb44a0aa7de771f2ebb4871-sciottir]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Chen, Helen Q. [b6]
Prabhavathi Fernandes [b6] Elsaid, Olivia [b6]
De wit, Emmie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634c7f8074f64222aad020f2950269c1-dewite]; [b6]
Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]

Subject: ACTIV Preclinical Network - Prioritization of Preclinical-stage agents

Start: 8/18/2020 3:00:00 PM

End: 8/18/2020 4:00:00 PM

Recurrence: (none)

-----Re-sending this invite as some of you have mentioned that you don't have it on your calendar-----

Hi all,

The objective of this meeting is to discuss the scoring for the 26 assigned preclinical agents. Also invited to this meeting is the team that put together the BSL 3 /4 network to support the discussion around next steps for these preclinical agents.

Look forward to the discussion on Tuesday 11am. If this time does not work for you, please let me know alternative time slots for 8/18 and 8/19. I will try my best to accommodate everyone's schedule.

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To: Alvarez, Rosa Maria [b6 Diamond, Michael [b6 Young, John
 b6 Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph
(NIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Gatto, Gregory
[b6 Mason, Stephen [b6 Baric, Ralph [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
Baric, Toni C [b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]
Subject: Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites
Start: 9/8/2020 3:00:00 PM
End: 9/8/2020 4:00:00 PM
Show Time As: Free

Recurrence: (none)

Hi all,

We will be canceling meetings for this sub-group and will rejoin as needed. For now, we will be consolidating into the Preclinical Network team that will be doing prioritization as well as support the match-making recommendations.

Best,
Rosa

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth
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[b6 Diamond, Michael [b6 Mason, Stephen [b6 Baric,
Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group
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[b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrat ve
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]
Subject: Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites
Start: 9/1/2020 3:00:00 PM
End: 9/1/2020 4:00:00 PM
Show Time As. Free

Recurrence: (none)

Hi all,

We will be canceling meetings for this sub-group and will rejoin as needed. For now, we will be consolidating into the Preclinical Network team that will be doing prioritization as well as support the match-making recommendations.

Best,
Rosa

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CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwood oh]

Subject: Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites

Start: 9/22/2020 3:00:00 PM
End: 9/22/2020 4:00:00 PM
Show Time As: Free

Recurrence: (none)

Hi all,

We will be canceling meetings for this sub-group and will rejoin as needed. For now, we will be consolidating into the Preclinical Network team that will be doing prioritization as well as support the match-making recommendations.

Best,
Rosa

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]
Subject: Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites
Start: 11/10/2020 4:00:00 PM
End: 11/10/2020 5:00:00 PM
Show Time As: Free

Recurrence: (none)

Hi all,

We will be canceling meetings for this sub-group and will rejoin as needed. For now, we will be consolidating into the Preclinical Network team that will be doing prioritization as well as support the match-making recommendations.

Best,
Rosa

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]
Subject: Canceled: ACTIV Preclinical - Network of BSL 3 / 4 sites
Start: 8/25/2020 3:00:00 PM
End: 8/25/2020 4:00:00 PM
Show Time As: Free

Recurrence: (none)

Hi all,

We will be canceling meetings for this sub-group and will rejoin as needed. For now, we will be consolidating into the Preclinical Network team that will be doing prioritization as well as support the match-making recommendations.

Best,
Rosa

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Sent: 7/22/2020 11:07:44 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh], Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: ACTIV graphics 1.0

Hi Karen,

This looks like a great start. A few minor comments/thoughts and responses to your questions:

- Should we keep all drug therapies separate? i.e. place antivirals in a bucket of its own? We would see a salmon colored dot twice. Maybe also include a bucket for other therapies which will be blank for the moment and include various vaccine treatment options (mRNA, protein, etc.)?
- I think the current model clearly indicates which compounds are being tested in the various population groups – if this was the original request or intent, Joe can confirm based on conversations with Maria and the war room. Current graphic doesn't make it clear to know which phase(s) the trials are in although I see the reference target on the bottom right. We discussed the option of showing the trial phases on the x-axis with the patient populations on the y-axis, and compounds on the z-axis but I do not have a preference here.
- Should we add additional population groups: emergency department, hospitalized ventilated vs. hospitalized non-ventilated, mild/moderate/severe disease? Only a thought, do we want to track recovery and include recovered patients eventually in a separate graphic?
- Should all of the dots be the same size (the salmon dot looks smaller but maybe it's my vision!)
- ACTIV-2 – they are starting with their phase 2 study. Subjects will be outpatient – is that outpatient asymptomatic or symptomatic or both? I would assume outpatient symptomatic but Stacey can confirm?
- ACTIV-4 – they have three protocols. I think we should track each separately. Your thoughts? Agree we should track them separately and they will launch/start enrollment at different times.
 - Need list of agents to be tested. I am happy to ask NHLBI contacts for this information unless we prefer to start with Stacey?
 - Need IND status: In-hospital was approved by the DSMB last week. Pre-hospital will be reviewed by the DSMB today 7/22. I do not know the IND status of the post-hospitalization—Stacey will likely have information.
- Need target enrollment numbers for each – I just stuck in numbers for illustrative purposes (see above). I have not seen the target enrollment numbers for ACTIV1-4, should we ask Stacey? I am happy to ask NHLBI for ACTIV-4 if needed.
- Need anticipated launch dates for each trial. I've only seen launch weeks: ACTIV 2-4 week of July 27, ACTIV-4 inpatient week of July 27, outpatient and post-hosp. is unclear to me, and ACTIV 1 - mid August.
- Enrollment tracker looks good to me!

Please let me know if we should start with Stacey for the remaining responses or if you prefer I contact NHLBI.

Thanks,
Ashley

From: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, July 22, 2020 5:27 PM
To: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6** Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: ACTIV graphics 1.0

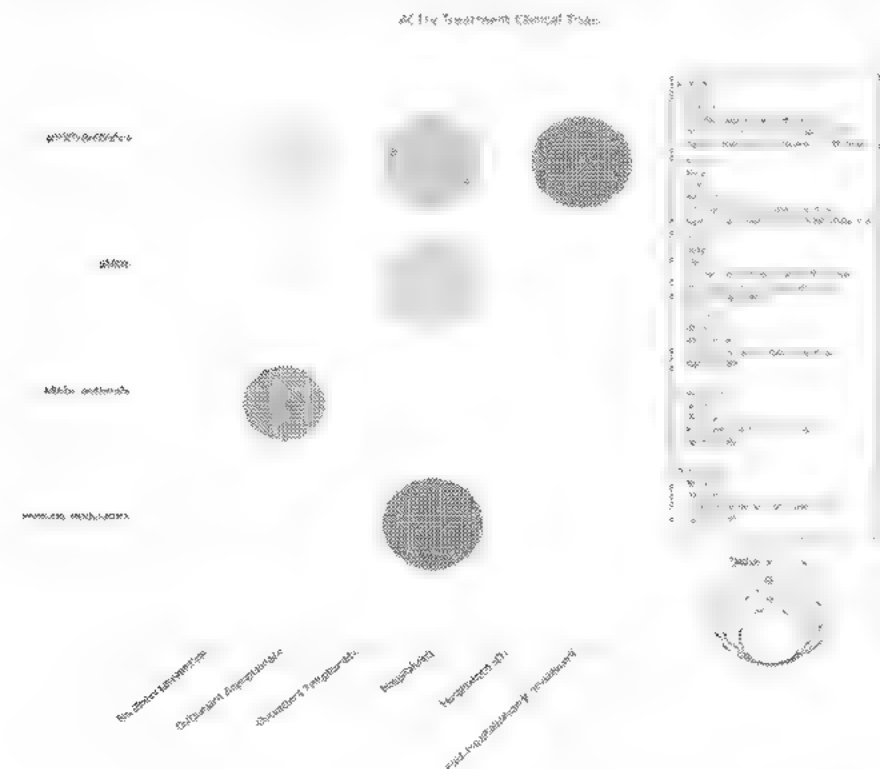
Hi Joe and Ashley,

I have been thinking about graphic representation for the ACTIV CT details and still like what we had talked about this morning, but excel does not allow creation of x/y/z scatter plots (or at least I cannot figure it out), so I made two plots:

- one for information about each trial (I'm a little iffy on this plot, it needs something...)
- and the other to track the status of enrollment versus the target (all numbers are just for demo – I don't have the real enrollment targets and obviously no subjects have enrolled yet.).

See what you think.

Of note, excel would not let me change the axis labels so these are just text boxes – not sure what was going on but...





Some of the information in the attached spreadsheet needs a bit more granularity as detailed below – do either of you have the answers?

- ACTIV-2 – they are starting with their phase 2 study. Subjects will be outpatient – is that outpatient asymptomatic or symptomatic or both?
- ACTIV-4 – they have three protocols I think we should track each separately. Your thoughts?
 - Need list of agents to be tested
 - Need IND status
- Need target enrollment numbers for each – I just stuck in numbers for illustrative purposes (see above)
- Need anticipated launch dates for each trial

Best,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
b6 fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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Sent: 5/11/2020 6:22:42 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Question re: ACTIV and BayCare Health System (Florida)

Sorry – updated email thread on this topic.

From: Higgins, Joni C. <[REDACTED]> **b6**
Sent: Monday, May 11, 2020 2:12 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Mauck, Daniel e <[REDACTED]> **b6**
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for making the connection.

Karen, David, it is nice to e-meet you. I am copying my colleague Danielle Mauck, who serves as BayCare's Director of Sponsored Programs and Research, to compare calendars.

We look forward to connecting with you to discuss your work and how we might help.

Joni

Joni Higgins
Federal Government Relations Manager

BayCare Health System
Cell: [REDACTED] **b6**
[REDACTED] **b6**

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, May 11, 2020 2:04 PM
To: Higgins, Joni C. <[REDACTED]> **b6** >
Cc: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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Hi Joni,

I am cc'ing Karen Tauntas and David Wholley with FNIH who are coordinating the efforts with ACTIV to find a time that best fits for you to speak with them.

Best,
Ashley

From: Higgins, Joni C. [REDACTED] b6
Sent: Monday, May 11, 2020 1:32 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for your note. I appreciate the quick follow-up. Do you think a call at some point this week might be a possibility?

Joni

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Sent: Monday, May 11, 2020 1:24 PM
To: Higgins, Joni C. [REDACTED] b6
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

WARNING: This email originated outside of BayCare. BE CAUTIOUS clicking links and opening attachments. Use the Report Phishing and Spam button to report malicious emails and contact the IS Service Desk with all other suspicious activity.

Hi Joni,

Thank you for sharing BayCare Health System's interest in becoming involved as a large non-profit hospital system with ACTIV. We are in the process of developing a portal to receive submissions from interested partners however in the meantime I am triaging these request for our working groups.

I've entered the information you've provided below into our database and will share this information with leads of our ACTIV clinical capacity working group to follow up with you.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [REDACTED] b6



National Institutes of Health

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APAR0000028764

Sent: 6/5/2020 6:35:31 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2bf13-walsher]; Rashid, Kamilah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce52e57bb74034834aa8660b5c8677-rashidkl]; Whitaker, Tiea (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80aed1a149c54d9b9d039fc6c2bed406-whitakerll]
Subject: RE: Preclinical and Tx Survey/Portal

Hi all,

We spoke with Christine Cutillo who's working closely with you all and Deloitte. We now have a better idea of the 2nd tier survey to gather additional information from companies regarding compounds and there's no need to pull time away from your schedules

From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Friday, June 5, 2020 7:58 AM
To: Colvis, Christine (NIH/NCATS) [E] <[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Menetski, Joseph (FNIH) [T] <[REDACTED]>
Cc: Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> Rashid, Kamilah (NIH/OD) [E] <[REDACTED]>
Whitaker, Tiea (NIH/NCATS) [C] <[REDACTED]>
Subject: RE: Preclinical and Tx Survey/Portal

Hi Ashley,

I am happy to make time as well. Agree both are necessary. Wednesday would be better for me if possible as we are using Monday to prepare for the mAb Summit Tuesday.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED], Mobile: [REDACTED]

From: Colvis, Christine (NIH/NCATS) [E] <[REDACTED]>
Sent: Friday, June 5, 2020 6:57 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> Menetski, Joseph (FNIH) [T] <[REDACTED]>
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]>; Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> Rashid, Kamilah (NIH/OD) [E] <[REDACTED]>; Whitaker, Tiea (NIH/NCATS) [C] <[REDACTED]>
Subject: RE: Preclinical and Tx Survey/Portal

Ashley,

I just realized that we hadn't gotten back to you. If still interested, I have some availability Monday and Wednesday. I'm cc'ing Tiera who keeps my calendar and can help find a time. What you are doing is definitely tier 1 and very complementary to what we are capturing with the ACTIV survey. Both are necessary.

Christine

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, June 3, 2020 1:00 PM
To: Menetski, Joseph (FNIH) [T] b6 ; Colvis, Christine (NIH/NCATS) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6 Walsh, Elizabeth (NIH/OD) [E] b6 Rashid, Kamilah (NIH/OD) [E] b6
Subject: Preclinical and Tx Survey/Portal

Hi Joe and Christine,

Can we find 15-20 mins to briefly chat about the 2nd tier survey/portal to receive additional information about compounds? I want to ensure NIH OD fully understands this process given we have the COVID portal as well.

Cc'ing Stacey as well.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: b6



National Institutes of Health

From: James, Stephanie (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0032EF62CA343DFB4BF79577E2AA8D1-JAMESST]
Sent: 4/23/2020 12:47:46 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]
Subject: FW: novel approach to COVID-19 vaccine

Dear Ashley,

I am one of the FNIH folks involved in the ACTIV project. I understand you are collating all the unsolicited offers for help on the project, and am forwarding the one below for your files.

Best regards,
Stephanie

Stephanie James, PhD FASTMH
Senior Vice President, Science
Foundation for the National Institutes of Health

b6

www.fnih.org

11400 Rockville Pike Suite 600, North Bethesda, MD 20852

From: Caroline Kurtz <[REDACTED]> b6
Sent: Wednesday, April 22, 2020 6:58 PM
To: James, Stephanie (FNIH) [T] <[REDACTED]> b6
Cc: Michaela Dankova <[REDACTED]> b6
Subject: novel approach to COVID-19 vaccine

Dear Stephanie,

I am reaching out to you as a contact on the FNIH site for information regarding grant opportunities for a COVID-19 vaccine. I lead programs at a small Biopharma company in Cambridge MA called Synlogic Inc (www.synlogictx.com), and we are interested in applying for funding to support development of a vaccine for COVID-19 using our platform. We especially need support to test safety and efficacy of the vaccine in preclinical models under BSL3 conditions. Our proposal is as follows:

Synlogic Inc. proposes to develop a vaccine for the prevention of COVID19 utilizing its synthetic biology platform to engineer probiotic bacteria to express viral antigens and immune activators/adjuvants. This vaccine will be based on an engineered E. coli Nissle (EcN) bacterial strain that will express viral proteins from SARS-CoV2, the causative agent for COVID-19, and can be administered intranasally to induce protective immunity systemically and at mucosal surfaces. This vaccine can be manufactured in our GMP facilities to produce millions of doses from a single batch. As a lyophilized bacterial cell product, it is expected to have good room temperature stability.

We would be in preclinical development of this vaccine candidate, but already have an engineered E. coli Nissle strain currently in clinical trials for oncology, that can be rapidly adapted for this purpose. The grant would allow us to engineer the strain and test it in preclinical models to get a candidate for clinical studies. Our questions are:

1. Is this project of interest to FNIH? (we could provide an abstract if you need to read more detail to know)
2. Is grant funding available for small businesses?
3. Would a phone call facilitate determining level of interest for this work?
4. What is the process to apply?

Thanks very much for your help and if I should direct my inquiry elsewhere, please advise.

Sincerely,

Caroline Kurtz

Caroline Kurtz, PhD
SVP, Head of Portfolio Strategy and Product Development
Synlogic Inc
301 Binney Street, Suite 402
Cambridge MA, 02142

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Sent: 3/3/2021 4:00:32 PM
To: Bugin, Kevin **b6**
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Hi Kevin,

I hope all is well given the breadth of activities happening simultaneously! Thank you for sharing the fact base information, this was useful to review what was captured from the interviews.

We learned of an interagency WG meeting led by USG therapeutics that took place this past Monday focused on doing a collective review of agents currently being tested and identifying any gaps with the prioritization process. Is this group one of the three lessons learned WG's discussed with the LT that will be led by ACTIV/NIH to review and develop actions for research, scoping, and prioritization or is this something else?

Thank you,
Ashley

From: Bugin, Kevin < **b6** >
Sent: Saturday, February 20, 2021 8:36 AM
To: Woodcock, Janet (FDA/OC) < **b6** > Marks, Gilbert (OS/ASPR/BARDA) (CTR)
< **b6** > Parker, Ashley (NIH/OD) [E] < **b6** > Adam, Stacey (FNIH) [T]
< **b6** > Armstrong, Kimberly (OS/ASPR/BARDA) < **b6** >
Cc: King, Mason < **b6** > Ramakrishnan, Raahul < **b6** > 'Roos, Jason W. SES
USARMY DOD JPEO CBRND (USA)' < **b6** >
Subject: RE: USG COV D-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Good morning Tx Lessons Learned Leadership Group,
Thanks for your time yesterday for the kick-off of our leadership group for the therapeutics lessons learned initiative focused on clinical evaluation. Based on our discussion it sounds like we are aligned on:

- objectives, scope, approach for working group (WG), and emerging themes.
- WG additions: TransCelerate, ACRO, Society of Clinical Research Sites, patient groups (via Duke)
 - If folks have any personal contacts at TransCelerate, ACRO, or SCRS, please let me know!
- Duke-Margolis on board with lead on breakout WG, as is ACTIV but with a different facilitator (not Stacey)
- Need to keep an eye out for internal learnings and strategy, ensure these are tracked but remain separate from external working groups

As discussed, attached please the current version of the LL fact base that has emerged from the engagements with USG to date, particularly NIH/ACTIV.

Please let me know if you have any questions.

Kevin

-----Original Appointment-----

From: Woodcock, Janet < **b6** >
Sent: Wednesday, February 10, 2021 1:51 PM
To: Woodcock, Janet; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Adam, Stacey J (NIH); Armstrong, Kimberly (OS)
Cc: King, Mason; Ramakrishnan, Raahul; 'Roos, Jason W. SES USARMY DOD JPEO CBRND (USA)'

Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

When: Friday, February 19, 2021 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex

Purpose: Align on scope and approach for the USG COVID-19 Therapeutics Lessons Learned initiative.

- Do not add or change any of the following information -

When it's time, join your Webex meeting here.



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<https://fda1.webex.com/>

b6

Join by meeting number

Meeting number (access code):

b6

Meeting password:

b6

Tap to join from a mobile device (attendees only)

b6

US Toll Free

US Toll

Join by phone

b6

US Toll

b6

US Toll Free

Toil-free calling restrnctions

If you are a host, click here to view host information.

Need help? Go to <https://help.webex.com>

Sent: 7/17/2020 3:07:28 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski];
Subject: RE: ACT Readout on Therapeutic Trials

Hi Stacey,

It was briefly explained that Gates/Wellcome are the workstream leads in the partnership to assess candidates and make selections (similar to the ACTIV prioritization WG) although the criteria used to determine which candidates would move forward was not shared. It seems they included candidates selected by ACT and noted RCT using the same compounds are

From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Friday, July 17, 2020 10:56 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> Collins, Francis (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Menetski, Joseph (FNIH) [T] <[REDACTED]>
Subject: RE: ACT Readout on Therapeutic Trials

Hi Ashley,

I had not seen this. This doesn't necessarily seem entirely comprehensive, but maybe I am not understanding the parameters for inclusion. It is a nice layout though.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] Mobile: [REDACTED]

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Friday, July 17, 2020 10:41 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]>

b6

> Adam, Stacey (FNIH) [T] <

b6

Menetski, Joseph (FNIH) [T]

b6

Subject: ACT Readout on Therapeutic Trials

Has anyone seen this?

FYI -- Phillipe Duneton, Unitaid presented this slide to the GLoPID-R Research Synergies meeting happening now. As you know, Unitaid is a partner with the WHO/Gates/Wellcome ACT- accelerator -- below is the readout on upcoming therapeutic trials.



Thanks,
Ashley

APAR0000028823

Sent: 5/6/2020 5:23:06 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
CC: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
Subject: RE: ACTIV Org slide for JAMA article.pptx
Attachments: ACTIV Leadership Slides 050620.pptx

Abort!! Please use this version – the first set had one slide and not two.

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 6, 2020 1:21 PM
To: George, Jill (NIH/OD) [E] < [REDACTED] b6 >
Cc: Kolberg, Rebecca (NIH/OD) [E] < [REDACTED] b6 >
Subject: RE: ACTIV Org slide for JAMA article.pptx

Attached is what will be shown this afternoon to ACTIV leadership – please see two slides.

- CDC addition to the ACTIV leadership team
- Vaccine CTs subgroup

Best,
Ashley

From: Collins, Francis (NIH/OD) [E] < [REDACTED] b6 >
Sent: Wednesday, May 6, 2020 11:30 AM
To: Parker, Ashley (NIH/OD) [E] < [REDACTED] b6 >
Cc: George, Jill (NIH/OD) [E] < [REDACTED] b6 >; Kolberg, Rebecca (NIH/OD) [E] < [REDACTED] b6 >; Berkson, Laura (NIH/OD) [E] < [REDACTED] b6 >
Subject: RE: ACTIV Org slide for JAMA article.pptx

Almost. One more tweak coming. Use the version that gets shown to ACTIV this afternoon.

From: Parker, Ashley (NIH/OD) [E] < [REDACTED] b6 >
Sent: Wednesday, May 6, 2020 11:02 AM
To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6 >
Cc: George, Jill (NIH/OD) [E] < [REDACTED] b6 >; Kolberg, Rebecca (NIH/OD) [E] < [REDACTED] b6 >; Berkson, Laura (NIH/OD) [E] < [REDACTED] b6 >
Subject: FW: ACTIV Org slide for JAMA article.pptx

Hi Francis,

Is this the version you would like to share for your Senate HELP hearing tomorrow?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] < [REDACTED] b6 >
Sent: Wednesday, May 6, 2020 10:37 AM
To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6 >; Tabak, Lawrence (NIH/OD) [E] < [REDACTED] b6 >;

Austin, Christopher (NIH/NCATS) [E] < [REDACTED] b6 Lane, Cliff (NIH/NIAID) [E] < [REDACTED] b6 Freire, Maria (FNIH) [T] [REDACTED] b6 ; Parker, Ashley (NIH/OD) [E] [REDACTED] b6 ; Anderson, James (NIH/OD) [E] [REDACTED] b6
Subject: RE: ACTIV Org slide for JAMA article.pptx

Yes, I caught those in the master deck. A bit hurried this morning... Here is the revised slide

From: Collins, Francis (NIH/OD) [E] < [REDACTED] b6
Sent: Wednesday, May 6, 2020 10:32 AM
To: Wholley, David (FNIH) [T] [REDACTED] b6 Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 >; Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6 ; Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 >; Freire, Maria (FNIH) [T] [REDACTED] b6 >; Parker, Ashley (NIH/OD) [E] < [REDACTED] b6 ; Anderson, James (NIH/OD) [E] [REDACTED] b6
Subject: RE: ACTIV Org slide for JAMA article.pptx

Quick fixes – Gary Gibbons (not Garry). And shouldn't the words "master protocol" appear in the bullets for the Vaccines WG?

FC

From: Wholley, David (FNIH) [T] < [REDACTED] b6
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6 >; Tabak, Lawrence (NIH/OD) [E] < [REDACTED] b6 >; Austin, Christopher (NIH/NCATS) [E] < [REDACTED] b6 Lane, Cliff (NIH/NIAID) [E] < [REDACTED] b6 Freire, Maria (FNIH) [T] [REDACTED] b6 ; Parker, Ashley (NIH/OD) [E] [REDACTED] b6 >; Anderson, James (NIH/OD) [E] [REDACTED] b6
Subject: ACTIV Org slide for JAMA article.pptx

Sent: 4/28/2020 3:08:34 PM
To: Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]
Subject: RE: ACTIV background slides
Attachments: ACTIV Partnership Leadership Team Meeting 20200422 Final 2.pdf

Hi Hilary,

Sounds like a great plan. Please see attached slides that were presented at the ACTIV leadership meeting on 4/22. We are in the process of updating slide 2 to include additional partners -- I will share once this is ready.

It may be a good idea to keep the lines of communication open between OD and NIAID to share materials that are presented outside of NIH. If you agree -- we can be the POCs for cross sharing.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Tuesday, April 28, 2020 10:54 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: ACTIV background slides

Thanks Ashley - We anticipate future congressional hearings for ASF and want to make sure messaging is consistent with Dr. Collins. Even just the bullet points from the slides would be fine (and we can make our own visuals)

On 4/28/20, 10:12 AM, "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> b6 wrote:

Hi Hilary,

We have slides that Francis has presented to the leadership group and we are editing a few slides for the WH briefing tomorrow. I think we can share some that we have but will need to know who will be using them and for what platform to ensure we are not duplicating.

Happy to chat if needed.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Tuesday, April 28, 2020 10:06 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: FW: ACTIV background slides

Ashley, do you have slides that would fit the bill?

On 4/28/20, 10:05 AM, "Wholley, David (FNIH) [T]" <[REDACTED]> b6 wrote:

Hilary, could I ask that you please contact Ashley Parker in OD about this?

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Tuesday, April 28, 2020 9:24 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: ACTIV background slides

David do you have any ACTIV overview slides handy? For a lay audience that is new to the PPP but savvy re COVID

Sent: 5/15/2020 11:49:33 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV Contacts
Attachments: Master and WG Email List for ACTIV rv 041620.xlsx

Hi David,

I hope this email finds you well. Yesterday was the first urgent request for the ACTIV email list; since then we've had a second request asking for the industry communications contacts – this has been taken care of but I want to ensure we are using the appropriate contacts whenever these types of request arise.

Given FNIH is managing the ACTIV list and private partners – can we work together to ensure we have an accurate list and maintain any updates as industry partners continue to join? I put together the attached spreadsheet using the information Cheryl provided yesterday. Also included are several tabs – master list, industry only contacts, contacts from April 3rd meetings, and 4 tabs for each of the working groups.

Can someone from your team ensure that our “industry only” list is accurate and let me know whenever we have additions? If a conversation would be helpful please let me know and I am happy to find a time – I just want to ensure we stay connected with contacts as ACTIV quickly moves forward.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: b6



National Institutes of Health

Sent: 5/30/2020 5:41:41 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: Tracking ACTIV Inquiries
Attachments: ACTIV Emails_Queries rv 050120.xlsx

Hi David,

Please see attached spreadsheet with updated ACTIV inquiries for this week.

Thanks,
Ashley

Sent: 5/15/2020 3:53:46 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV Work Flowdw.pptx

Thanks, David. I

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Friday, May 15, 2020 11:28 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Freire, Maria (FNIH) [T] <[REDACTED]> **b6**
Subject: ACTIV Work Flowdw.pptx

Hi, Ashley, please see my suggested changes to this slide in comments. Happy to discuss further

Sent: 4/28/2020 2:12:43 PM
To: Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]
Subject: RE: ACTIV background slides

Hi Hilary,

we have slides that Francis has presented to the leadership group and we are editing a few slides for the WH briefing tomorrow. I think we can share some that we have but will need to know who will be using them and for what platform to ensure we are duplicating.

Happy to chat if needed.

Thanks,
Ashley

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <[REDACTED]> **b6**
Sent: Tuesday, April 28, 2020 10:06 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: ACTIV background slides

Ashley, do you have slides that would fit the bill?

On 4/28/20, 10:05 AM, "Wholley, David (FNIH) [T]" <[REDACTED]> **b6** wrote:

Hilary, could I ask that you please contact Ashley Parker in OD about this?

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] <hilary.[REDACTED]> **b6**
Sent: Tuesday, April 28, 2020 9:24 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: ACTIV background slides

David do you have any ACTIV overview slides handy? For a lay audience that is new to the PPP but savvy re COVID

Sent: 5/6/2020 5:12:57 PM
Subject: FW: ACTIV Org slide for JAMA article.pptx
Attachments: ACTIV Leadership slide_Executive Comm..pptx

Attached is what will be shown this afternoon. Master protocol has been removed.

Best,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 6, 2020 11:30 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: George, Jill (NIH/OD) [E] <[REDACTED]> **b6** Kolberg, Rebecca (NIH/OD) [E] <[REDACTED]> **b6** Berkson, Laura (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Org slide for JAMA article.pptx

Almost. One more tweak coming. Use the version that gets shown to ACTIV this afternoon.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 6, 2020 11:02 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Cc: George, Jill (NIH/OD) [E] <[REDACTED]> **b6** Kolberg, Rebecca (NIH/OD) [E] <[REDACTED]> **b6** Berkson, Laura (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: ACTIV Org slide for JAMA article.pptx

Hi Francis,

Is this the version you would like to share for your Senate HELP hearing tomorrow?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, May 6, 2020 10:37 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6** Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> **b6** Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6** Freire, Maria (FNIH) [T] <[REDACTED]> **b6** >, Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Anderson, James (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Org slide for JAMA article.pptx

Yes, I caught those in the master deck. A bit hurried this morning... Here is the revised slide

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 6, 2020 10:32 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6** Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6** >; Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> >; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6** >; Freire, Maria (FNIH) [T] <[REDACTED]> **b6** Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Anderson, James (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Org slide for JAMA article.pptx

Quick fixes – Gary Gibbons (not Garry). And shouldn't the words "master protocol" appear in the bullets for the Vaccines WG?

FC

From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] b6 > Tabak, Lawrence (NIH/OD) [E] b6 >
Austin, Christopher (NIH/NCATS) [E] b6 Lane, Cliff (NIH/NIAID) [E] b6 > Frelre,
Maria (FNIH) [T] b6 > Parker, Ashley (NIH/OD) [E] b6 : Anderson, James (NIH/OD)
[E] < b6
Subject: ACTIV Org slide for JAMA article.pptx

Sent: 5/21/2020 11:08:22 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Parker Institute
Attachments: Notes Meeting with UCLA_Sean Parker et al. May 21, 2020.docx

Attached are my notes from the call

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, May 21, 2020 6:53 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6** Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Parker Institute

Yikes.

Sent: 5/15/2020 11:49:33 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: Need to know how to reach your comms contacts
Attachments: Master list for ACTIV 041520.xlsx; RE: List -- just copy and paste in bcc. Lists of April 3 plus working groups

Here is the complete list I shared yesterday.

I shared this list with Renate this morning and will update her with any changes we receive from FNIH.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, April 16, 2020 9:23 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Need to know how to reach your comms contacts

Done. Let's be sure we have the complete lists together for the future.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, April 16, 2020 8:52 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Myles, Renate (NIH/OD) [E] <[REDACTED]>
Subject: RE: Need to know how to reach your comms contacts

Andy Plump was one of the reps inadvertently left off of FNIH's first list.

Here are 2 others: Paul Steve and David Payne who should be included – this should be everyone.

Paul, Steve [REDACTED] **b6**
Payne, David [REDACTED] **b6**

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, April 16, 2020 8:10 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Need to know how to reach your comms contacts

I used the bcc e-mail list that came with the request to send the message – see attached, this was also cc'd to you last night.

I don't see Andy Plump's name. I will send this to him right now. Are there any others missing?

FC

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Thursday, April 16, 2020 7:47 AM
To: Collins, Francis (NIH/OD) [E] b6
Subject: RE: Need to know how to reach your comms contacts

Good morning Francis,

Were you able to use our ACTIV master email list for the note you sent below? OCPL wants to confirm that our rep from Takeda received this -- Plump, Andy b6

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] b6
Sent: Wednesday, April 15, 2020 9:39 PM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Myles, Renate (NIH/OD) [E] <b6>; Parker, Ashley (NIH/OD) [E] b6; Burklow, John (NIH/OD) [E] <b6> Wholley, David (FNIH) [T] <b6> Meltzer, Abbey (FNIH) [T] b6
Subject: Need to know how to reach your comms contacts
Importance: High

Dear ACTIV colleagues (once again, that's you in the bcc line):

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at b6 and Abbey Meltzer (b6) this evening, if possible.

Many thanks, Francis

Sent: 5/11/2020 2:54:36 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: Viewpoint on ACTIV
Attachments: JAMA ACTIV Clean_051120.docx

Looping in David regarding the question below.

From: Howard Bauchner <[REDACTED]> **b6**
Sent: Monday, May 11, 2020 10:24 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Phil Fontanarosa <[REDACTED]> **b6**; Stoffels, Paul <[REDACTED]> **b6**; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Viewpoint on ACTIV

Francis/Paul

Thinking it would be helpful to name the folks from industry you have collaborated with at the end of the article – in additional information – suspect most readers will want to know who.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, May 11, 2020 9:03 AM
To: Howard Bauchner <[REDACTED]> **b6** >
Cc: Phil Fontanarosa <[REDACTED]> **b6**; Stoffels, Paul <[REDACTED]> **b6**; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Viewpoint on ACTIV

[Warning External Email]
Here you go. Many thanks for your very rapid response!!

Best, Francis

From: Howard Bauchner <[REDACTED]> **b6** >
Sent: Sunday, May 10, 2020 1:47 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Phil Fontanarosa <[REDACTED]> **b6**
Subject: Re: Viewpoint on ACTIV

Francis – attached are our edits –

Just return a clean copy and one with track changes to Phil and me.

Stay healthy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

From: Francis Collins **b6**
Date: Sunday, May 10, 2020 at 11:32 AM
To: Howard Bauchner < **b6** >
Cc: "Stoffels, Paul" < **b6** >, "Tabak, Lawrence (NIH/OD) [E]" **b6** >, Tony
Fauci **b6** >, "Burklow, John (NIH/OD) [E]" **b6** >, "Myles, Renate (NIH/OD)
[E]" < **b6** >, "Parker, Ashley (NIH/OD) [E]" **b6** >, "Kolberg, Rebecca
(NIH/OD) [E]" **b6** >, "Wolinetz, Carrie (NIH/OD) [E]" **b6** >, "Wholley,
David (FNIH) [T]" < **b6** >, "Freire, Maria (FNIH) [T]" < **b6** >
Subject: Viewpoint on ACTIV

[Warning External Email]

Dear Howard,

On behalf of Paul Stoffels and myself, please see attached a Viewpoint on the ACTIV public-private partnership that we would like to have considered for publication in JAMA. Because of the rapidly moving events surrounding the COVID-19 pandemic, your offer to review this quickly is much appreciated.

I will serve as corresponding author.

Many thanks, Francis

Sent: 4/16/2020 12:48:26 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: Need to know how to reach your comms contacts
Attachments: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

Andy Plump was one of the reps that was left off of FNIH's first list. Here are 2 others Paul Steve and David Payne were also not included in FC's email.

Paul Steve b6
Payne, David < b6

From: Collins, Francis (NIH/OD) [E] < b6
Sent: Thursday, April 16, 2020 8:10 AM
To: Parker, Ashley (NIH/OD) [E] < b6
Cc: Myles, Renate (NIH/OD) [E] < b6
Subject: RE: Need to know how to reach your comms contacts

I used the bcc e-mail list that came with the request to send the message -- see attached, this was also cc'd to you last night.

I don't see Andy Plump's name. I will send this to him right now. Are there any others missing?

FC

From: Parker, Ashley (NIH/OD) [E] b6 >
Sent: Thursday, April 16, 2020 7:47 AM
To: Collins, Francis (NIH/OD) [E] b6
Subject: RE: Need to know how to reach your comms contacts

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Thanks,
Ashley

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Sent: Wednesday, April 15, 2020 9:39 PM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Myles, Renate (NIH/OD) [E] - Parker, Ashley (NIH/OD) [E] < b6 Burklow, John (NIH/OD) [E] b6 Wholley, David (FNIH) [T] < b6 ; Meltzer, Abbey (FNIH) [T] b6
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Many thanks, Francis

Sent: 5/11/2020 12:52:13 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Stoffels, Paul [JJCUS] [b6]
Subject: RE: Viewpoint on ACTIV
Attachments: JAMA ACTIV 050920 5-11-2020.docx

Hi Francis,

Please see the attached changes FNIH provided below in addition to the update on the number of identified networks by the clinical capacity WG – now “44”.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Monday, May 11, 2020 8:12 AM
To: Parker, Ashley (NIH/OD) [E] <[b6]> Collins, Francis (NIH/OD) [E] <[b6]>
Cc: Stoffels, Paul [JJCUS] <[b6]>
Subject: RE: Viewpoint on ACTIV

Hi Ashley:

Yes, please remove “vaccines” from the Clinical Tx working group description.

In the vaccines description, in the vaccines section we suggest that “This includes development of a harmonized master protocol for adaptive trials of **three or more** vaccines” to “This includes development of a harmonized master protocol for adaptive trials of **multiple** vaccines.” I don’t think we want to hem ourselves in by saying 3 or more.

I have a call in to Karen Tountas to confirm the number of sites (38) mentioned in the Clinical Trial Capacity WG so I can get you the latest updated number. Those are the only changes from us.
David

From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Sunday, May 10, 2020 7:01 PM
To: Collins, Francis (NIH/OD) [E] <[b6]> Wholley, David (FNIH) [T] <[b6]>
Cc: Stoffels, Paul [JJCUS] <[b6]>
Subject: RE: Viewpoint on ACTIV

Hi Francis,

Looks fine but would only flag a few minor items to be confirmed. David – could your team confirm the items below?

- **The Clinical Therapeutics Working Group:** “To help achieve these goals, the group has established a steering committee with relevant expertise and objectivity to set criteria for evaluating and ranking potential candidate therapies and vaccines submitted by industry partners.”

- Is the agreement to have the clinical Tx WG evaluate and rank “vaccines”? Only confirming considering I understood the vaccine group would prioritize vaccine candidates using special criteria?
- **The Vaccines Working Group:** “This includes development of a harmonized master protocol for adaptive trials of three or more vaccines....”
 - There were discussions over the weekend regarding the master protocol for vaccines – uncertain of the final decision. Individual harmonized protocols?

Thank you for the opportunity to review.
Ashley

From: Stoffels, Paul [JICUS] b6
Sent: Sunday, May 10, 2020 2:32 PM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Parker, Ashley (NIH/OD) [E] < >; Wholley, David (FNIH) [T] < b6
Subject: Re: Viewpoint on ACTIV

All good. Please go ahead. Thanks for taking the lead. This is going to be a great partnership.

Have a bit of a relaxed sunday !

Paul

Verstuurd vanaf mijn iPad

Op 10 mei 2020 om 20:05 heeft Collins, Francis (NIH/OD) [E] b6 het volgende geschreven:

Hi Paul,

I don't think I've ever seen a manuscript edited and returned in two hours! We must be working on something important.

The edits seem to be purely cosmetic. Please have a quick look, however, to be sure that there is no violence done to the meaning. I will do the same. I'm also cc'ing Ashley and David – and asking that they look closely at the description of the actions of the Working Groups, as well as the Figure, since ACTIV progress has been advancing almost by the hour.

If we can get this back to JAMA today, that would be great.

Thanks, Francis

From: Howard Bauchner < b6
Sent: Sunday, May 10, 2020 1:47 PM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Phil Fontanarosa < b6
Subject: Re: Viewpoint on ACTIV

Francis – attached are our edits –

Just return a clean copy and one with track changes to Phil and me.

Stay healthy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my chats with authors

From: Francis Collins [b6]
Date: Sunday, May 10, 2020 at 11:32 AM
To: Howard Bauchner <[b6]>
Cc: "Stoffels, Paul" [b6], "Tabak, Lawrence (NIH/OD) [E]"
<[b6]>, Tony Fauci <[b6]>, "Burklow, John (NIH/OD) [E]"
<[b6]>, "Myles, Renate (NIH/OD) [E]" [b6], "Parker, Ashley
(NIH/OD) [E]" [b6], "Kolberg, Rebecca (NIH/OD) [E]"
[b6], "Wolinetz, Carrie (NIH/OD) [E]" [b6],
"Wholley, David (FNIH) [T]" <[b6]>, "Freire, Maria (FNIH) [T]"
[b6]
Subject: Viewpoint on ACTIV

[Warning External Email]

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I will serve as corresponding author.

Many thanks, Francis

<JAMA ACTIV_050920 5 10 2020.docx>

<JAMA ACTIV Figure_050920.docx>

Sent: 5/6/2020 2:58:23 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolberg]; Berkson, Laura (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=adb561ab47e54fdc94e2a54682514434-berksonid]
Subject: FW: ACTIV Org slide for JAMA article.pptx
Attachments: ACTIV Org slide for JAMA article.pptx

Hi Francis,

Is this the version you would like to share for your Senate briefing tomorrow?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, May 6, 2020 10:37 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6** Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> **b6** Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6** Freire, Maria (FNIH) [T] <[REDACTED]> **b6** Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Anderson, James (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Org slide for JAMA article.pptx

Yes, I caught those in the master deck. A bit hurried this morning... Here is the revised slide

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 6, 2020 10:32 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6** Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6** Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> **b6** >; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6** Freire, Maria (FNIH) [T] <[REDACTED]> **b6** ; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** ; Anderson, James (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Org slide for JAMA article.pptx

Quick fixes – Gary Gibbons (not Garry). And shouldn't the words "master protocol" appear in the bullets for the Vaccines WG?

FC

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6** Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> **b6** >; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6** Freire, Maria (FNIH) [T] <[REDACTED]> **b6** Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** >; Anderson, James (NIH/OD) [E] <[REDACTED]> **b6**
Subject: ACTIV Org slide for JAMA article.pptx

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/28/2020 10:59:18 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: Recall: Update ACTIV Partner Slide

Parker, Ashley (NIH/OD) [E] would like to recall the message, "Update ACTIV Partner Slide".

Sent: 5/6/2020 2:25:10 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Thanks, David! Is the only change to include master protocol for the vaccine group – please see attached. We need to submit this for use in Francis’ congressional briefing slide for toroow.

Thank you,
Ashley

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6** Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> **b6** Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6** Freire,
Maria (FNIH) [T] <[REDACTED]> **b6** Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Anderson, James (NIH/OD)
[E] <[REDACTED]> **b6**
Subject: ACTIV Org slide for JAMA article.pptx

Sent: 4/24/2020 9:23:33 PM
To: Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
CC: Whitfield, Michelle D. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e428ea1fdc574614bcd5c42548b50c86-whitfieldmd]
Subject: RE: ACTIV Proposal for COVID lung injury
Attachments: RE: A proposal to stop COVID-19 and reopen our schools and businesses

Hi Rachel,

This is awesome – thank you! Dr. Wolinetz has also indicated to FNIH that ES will be handling the email request received and not OSP (see attached) – you may begin receiving queries via a forwarded email. I looped you in on this one as I wanted to acknowledge receipt of the ACTIV request but do not have the bandwidth to upload at the moment due to another urgent assignment I am working on.

Thanks so much,
Ashley

From: Pollock, Rachel (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, April 24, 2020 5:17 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Whitfield, Michelle D. (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Proposal for COVID lung injury

Ashley –

This afternoon I initiated our new process on the ES end, meaning that CoS, OSP, and NIAID should begin receiving FYI copies of ACT V inquiries for your review, and I sent out the first batch of acknowledgment emails. Please let me know if you see any need for tweaks as this system progresses.

Rachel Pollock

O: [REDACTED] **b6**
C: [REDACTED] **b6**

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, April 24, 2020 5:00 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**, Pollock, Rachel (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Proposal for COVID lung injury

Received – thank you.

Ashley

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Friday, April 24, 2020 4:56 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**, [REDACTED] **rg**
Subject: FW: ACTIV Proposal for COVID lung injury

From: Gabor Illei [REDACTED] b6
Sent: Friday, April 24, 2020 4:30 PM
To: Wholley, David (FNIH) [T] [REDACTED] b6
Subject: ACTIV Proposal for COVID lung injury

Dear David,

Kristina Lu from NIAID suggested I contact you. I am VP of clinical development at Viela Bio, a biotechnology company in Gaithersburg with a focus on autoimmune diseases. We believe that there is a strong rationale supporting the potential of one of our clinical stage assets to prevent or treat the hyperinflammatory syndrome leading to acute lung injury in COVID patients. I read with great interest about the ACTIV initiative and would like to find out more about how proposals can be submitted for consideration for ACTIV. Can you provide me some information or direct me to where I can get this information?

Thank you very much.
Best regards,
Gabor

Gábor Illei, MD, PhD, MHS
Vice President
Clinical Development Lead



Tel: [REDACTED] b6

From: Lu, Kristina (NIH/NIAID) [E] [REDACTED] b6
Sent: Wednesday, April 22, 2020 6:35 PM
To: Gabor Illei [REDACTED] b6
Cc: Bill Rees [REDACTED] b6 ; Michael Smith [REDACTED] b6 ; Ilias Alevizos [REDACTED] b6 ; Sandra Gallagher [REDACTED] b6 >
Subject: Re: Proposal for VIB7734 for COVID lung injury

EXTERNAL. Do not open attachment(s) unless you know the content is safe.

Hello Gabor,

There was a recent [NIH news release](#) regarding the ACTIV partnership. For additional information, please contact David Wholley ([REDACTED] b6) who is the FNIH Contact for ACTIV (Public-Private Partnership Initiative).

--Kristina

From: Gabor Illei [REDACTED] b6
Date: Wednesday, April 22, 2020 at 11:48 AM
To: "Lu, Kristina (NIH/NIAID) [E]" [REDACTED] b6
Cc: Bill Rees <[REDACTED] b6> ; Michael Smith <[REDACTED] b6> ; Ilias Alevizos

b6

>, Sandra Gallagher <ga

b6

Subject: RE: Proposal for VIB7734 for COVID lung injury

Dear Kristina,

I would like to follow up to see if the NIAID's SARS-CoV-2/COVID-19 research team had a chance to review our proposal for the prevention and treatment of COVID-19 associated acute lung injury. We are not primarily looking funding but for an effective mechanism where we could test our asset in an expeditious an effective way. We read with great interest about the ACTIV initiative organized by the NIH but were unable to find any specifics about how one could submit a proposal or an asset to this program. Can you give us some advice on how to apply or who to contact to find out more details?

Any advice is greatly appreciated.

Thank you and best regards,

Gabor

Gábor Illei, MD, PhD, MHS

Vice President

Clinical Development Lead



b6

Tel: b6

From: Gabor Ille

Sent: Monday, April 13, 2020 5:45 PM

To: Lu, Kristina (NIH/NIA D) [E] <b6

Cc: Bill Rees <b6>; Michael Smith <b6> Ilias Alevizos <b6>

Sandra Gallagher <b6

Subject: RE: Proposal for VIB7734 for COVID lung injury

Dear Kristina,

Thank you for the prompt response. We are looking forward to hearing some feedback NIAID's SARS-CoV-2/COVID-19 research team. We will also look at the IDCRC website.

Best regards,

Gabor

From: Lu, Kristina (NIH/NIAID) [E] <b6

Sent: Monday, April 13, 2020 5:06 PM

To: Gabor Illei <b6>

Cc: Bill Rees <b6>, Michael Smith <b6> Ilias Alevizos <b6>

Sandra Gallagher <b6

Subject: Re: Proposal for VIB7734 for COVID lung injury

EXTERNAL. Do not open attachment(s) unless you know the content is safe.

APAR0000029004

Hello Dr. Illei,

Thank you for your message regarding a clinical trial with VIB7734 for the prevention and treatment of COVID-19 associated lung injury and sharing your slide decks. Your email will be shared with NIAID's SARS-CoV-2/COVID-19 research team.

NIAID supports clinical trials through our [Infectious Diseases Clinical Research Consortium \(IDCRC\)](https://med.emory.edu/departments/medicine/divisions/infectious-diseases/idcrc/concept.html) and our investigator-initiated clinical trial grant programs. The IDCRC recently launched a website for investigators interested in submitting concepts for consideration. This website is <https://med.emory.edu/departments/medicine/divisions/infectious-diseases/idcrc/concept.html>

For investigator-initiated grants, we are directing PIs to the parent mechanisms listed below:

- [NIAID Clinical Trial Implementation Cooperative Agreement \(U01, Clinical Trial Required\)](#)
- **Parent R01 announcement:**
 - [NIH Research Project Grant \(Parent R01 Basic Experimental Studies with Humans Required\)](#)
 - [Research Project Grant \(Parent R01 Clinical Trial Required\)](#)
- **Parent R21 announcement:**
 - [NIH Exploratory/Developmental Research Grant Program \(Parent R21 Basic Experimental Studies with Humans Required\)](#)
 - [NIH Exploratory/Developmental Research Grant Program \(Parent R21 Clinical Trial Required\)](#)

Funding opportunities are also available from other NIH Institutes and Centers. Please see the table on this website https://grants.nih.gov/grants/natural_disasters/corona-virus.htm.

Kind regards,
Kristina

--
Kristina T. Lu, PhD
Program Officer
Respiratory Diseases Branch
Division of Microbiology & Infectious Diseases
NIAID | NIH | DHHS

Phone: b6
b6

Disclaimer: The information in this email and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the originally intended recipient. If you have received this email in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of NIAID by one of its representatives.

From: Gabor Illei b6
Date: Monday, April 13, 2020 at 12:32 PM
To: "Lu, Kristina (NIH/NIAID) [E]" <b6> "Bozick, Brooke (NIH/OD) [E]"
b6
Cc: Bill Rees b6 >, Michael Smith b6 Ilias Alevizos
b6 Sandra Gallagher <b6>
Subject: FW: Proposal for VIB7734 for COVID lung injury

Dear Drs. Lu and Bozick,

I am the VP for clinical development of VielaBio, a biotechnology company in Gaithersburg with a focus on autoimmune diseases. We believe that there is a strong rationale supporting the potential of one of our clinical stage assets (a plasmacytoid depleting cell antibody) to prevent or treat the hyperinflammatory syndrome leading to acute lung injury in COVID patients.

We would like to test our asset in clinical trials as soon as possible and wanted to ask if NIAID had any mechanisms to facilitate a clinical trial. Could this molecule be considered for a platform study? Are there any other options for early stage molecules? (We are currently completing dosing in the last cohort of cutaneous lupus patients in a multiple ascending dose Phase 1b study).

I attached a brief high level description of our plans and a slide deck with more details on the rationale and plans. These slides were also submitted to BARDA and we submitted an application to the FDA CTAP program. Please note that the attached slides contain Viela's confidential information. As is usually expected, please protect the confidentiality of these slides just as you do for your institution's confidential information and please do not share the slides without asking Viela first

We are not currently and have not in the past received any NIH funding.

Please let me know if you have any questions. I am looking forward to your response, we would greatly appreciate any information.

Thank you and best regards,
Gabor

Gábor Illei, MD, PhD, MHS
Vice President
Clinical Development Lead



Tel: (**b6**) **b6**

From: Read, Sarah (NIH/NIAID) [E] **b6**
Sent: Thursday, April 9, 2020 11:14 AM
To: Gabor Illei **b6** Michael Smith **b6**
Cc: Bill Rees **b6**
Subject: RE: Proposal for VIB7734 for COVID lung injury

EXTERNAL. Do not open attachment(s) unless you know the content is safe.

Hi again Gabor and Mike,
I apologize for the delay getting back to you. Please contact Kristina Lu **b6** and Brooke Bozick **b6** at the Division of Microbiology and Infectious Diseases to make this inquiry.

Best wishes,
Sarah

From: Read, Sarah (NIH/NIAID) [E]
Sent: Monday, April 6, 2020 7:58 AM
To: Gabor Illei **b6** >; Michael Smith **b6**

Cc: Bill Rees [REDACTED] b6

Subject: RE: Proposal for VIB7734 for COVID lung injury

Hi Gabor and Mike, I'm just waiting on a contact from Division of Microbiology and Infectious Diseases. They are reorganizing a bit given how many inquiries they are receiving and are identifying a new contact for immunotherapies. Will send you contact information later today.

Best,
Sarah

From: Gabor Illei [REDACTED] b6 >

Sent: Sunday, April 5, 2020 11:28 AM

To: Read, Sarah (NIH/NIAID) [E] [REDACTED] b6 >; Michael Smith [REDACTED] b6

Cc: Bill Rees [REDACTED] b6

Subject: RE: Proposal for VIB7734 for COVID lung injury

Dear Sarah,

Thank you for your prompt response. Mike, thank you for making the connection.

To answer your question, we are not currently and have not in the past received any NIH funding. We have submitted a BARDA TechWatch meeting request and will apply to the FDA CTAP program. We are also trying to explore any other possibilities which may facilitate starting a clinical study.

Any suggestion would be greatly appreciated.

Thank you,
Gabor

Gábor Illei, MD, PhD, MHS
Vice President
Clinical Development Lead



[REDACTED] b6

Tel: [REDACTED] b6

From: Read, Sarah (NIH/NIAID) [E] [REDACTED] b6

Sent: Sunday, April 5, 2020 10:58 AM

To: Michael Smith <[REDACTED] b6>

Cc: Bill Rees [REDACTED] b6 ; Gabor Illei [REDACTED] b6

Subject: Re: Proposal for VIB7734 for COVID lung injury

EXTERNAL. Do not open attachment(s) unless you know the content is safe.

Hi Mike.

Thank you for your email. All is well with us, relatively speaking. We're adjusting to a new normal and hoping/waiting for things to improve.

This is not exactly my purview. As you know my division's primary focus is HIV but like many research organizations we've pivoted to SARS-COV2 research but mainly evaluation of interventions approved for other indications (eg

hydroxychloroquine, remdesivir, etc). However I can find the appropriate NIAID contact for you. Will you tell me first do you have any current NIH funding of any kind (not specifically for SARS-COV2) or have you previously?

Thank you for your interest in helping with the SARS-COV2 response.

Best,
Sarah

From: "Michael Smith" <[REDACTED]>
Date: Saturday, April 4, 2020 at 10:19:11 PM
To: "Read, Sarah (NIH/NIAID) [E]" <[REDACTED]>
Cc: "Bill Rees" <[REDACTED]>, "Gabor Illei" <[REDACTED]>
Subject: Proposal for VIB7734 for COVID lung injury

Hi Sarah!

This is Mike Smith, [REDACTED]. I hope you and your family are doing well. We are doing pretty good over here, although [REDACTED] is starting to see some patients infected with SARS-CoV-2 at her ER in [REDACTED] right now. I'm a little worried about her. I'm glad you all have [REDACTED] pretty well taken care of.

I am sorry to bother you during what has to be an extremely busy time, but we would like to ask for your advice on how to advance one of our clinical stage assets (a plasmacytoid depleting cell antibody) to clinical trial to prevent or treat COVID associated lung injury. I attached both a brief summary of the proposal and an expanded powerpoint deck with more details. I've also cc'd Gabor Illei, our Vice President of Clinical Development, and Bill Rees, head of Translational Sciences here at Viela Bio.

If this is outside your purview could you advise who best to contact or feel free to forward this message or deck.

My apologies again for bothering you. We are eager to find out if we can help somehow in the fight against COVID.
Thank you!
Mike Smith

Please note that the attached slides contain Viela's confidential information. As is usually expected, please protect the confidentiality of these slides just as you do for your institution's confidential information and please do not share the slides without asking Viela first.

From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 4/24/2020 11:51:19 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]
CC: Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]
Subject: RE: A proposal to stop COVID-19 and reopen our schools and businesses

Thanks, David. Just FYI, there is a formal system run by our Executive Secretariat for assigning response to emails or correspondence that comes into Francis. It is not an OSP function. Cheers, Carrie

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health (NIH)

b6

<http://osp.od.nih.gov/>

Please follow on Twitter: @CWolinetzNIH



National Institutes of Health
Turning Discovery Into Health

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, April 23, 2020 10:28 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6 Jorgenson, Lyric (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: A proposal to stop COVID-19 and reopen our schools and businesses

Thanks, David. I've seen this email — since it was sent directly to Francis.

I'm cc'ing Carrie and Lyric for awareness.

Thanks again,
Ashley

On Apr 23, 2020, at 9:51 PM, Wholley, David (FNIH) [T] <[REDACTED]> b6 wrote:

For logging with your other inquiries. As I have mentioned before, FNIH views formal group appeals to the NIH Director as an issue for NIH OSP to handle.

From: David Liu <[REDACTED]> b6
Sent: Thursday, April 23, 2020 6:01 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]> b6 Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Austin, Christopher

APAR0000029005

{NIH/NCATS} [E] < b6 Wholley, David (FNIH) [T] < b6 Freire, Maria
{FNIH} [T] < b6 Tabak, Lawrence (NIH/OD) [E] < b6
Cc: Michael Rosbash < b6 Ramnik Xavier < b6
EDWARD SCOLNICK < b6 Stuart Schreiber b6 Michael Z Lin
< b6 Ben Cravatt < b6 Thomas Cahill < b6
R. Scott Kemp < b6

Subject: Re. A proposal to stop COVID-19 and reopen our schools and businesses

Dear Francis, Anthony, Cliff, Christopher, David, Maria, and Lawrence,

I hope you are all well. Attached is the updated set of four proposals on:

- 1) Rapid repurposing of antiviral drugs to treat COVID-19;
- 2) Expedited development of neutralizing monoclonal antibodies to treat COVID-19;
- 3) Rapid COVID-19 vaccine development;
- 4) Risk reduced ways to reopen schools and businesses, and the healthcare system changes that are needed to enable them.

We hope you find these updated proposals useful, and would be happy to engage in any way that could be helpful.

Sincerely yours,

Ben Cravatt (Scripps), Lynn Goldman (GWU), Akiko Iwasaki (Yale), Scott Kemp (MIT), Michael Lin (Stanford), David Liu (Harvard/Broad), Michael Rosbash (Brandeis), Stuart Schreiber (Harvard/Broad), Ed Scolnick (Broad), Jonathan Simons (PCF), and Ramnik Xavier (MGH/Broad)

David R. Liu
Richard Merkin Professor and Director of the Merkin Institute
of Transformative Technologies in Healthcare
Director of the Chemical Biology and Therapeutic Sciences Program
Core Institute Member and Vice-Chair of the Faculty, Broad Institute
Investigator, Howard Hughes Medical Institute
Thomas Dudley Cabot Professor of the Natural Sciences
and Professor of Chemistry & Chemical Biology, Harvard University
75 Ames Street
Cambridge, MA 02142

On Apr 19, 2020, at 8:48 PM, Collins, Francis (NIH/OD) [E] < b6 wrote:

Dear David et al.,

Thanks for forwarding this very thoughtful document, which presents a series of important recommendations – most of which I agree with. I don't know if you saw Friday's announcement (attached) of the new public private partnership called ACTIV (for Accelerating COVID-19 Therapeutic Interventions and Vaccines), but it has taken on most of the points you raise in sections 1 – 3 of your letter. I share your hopes that remdesivir will show benefit, and the current large NIH-sponsored RCT has completed enrollment and should reveal results in about a month. But of course we want to test multiple other interventions – both small molecules and antibody-based therapies, so we need our trial system to be optimized like never before. I will share your letter with the leaders of

ACTIV, who are working with unprecedented speed to prioritize the next set of therapeutic candidates as well as pushing vaccine development programs to adopt exceptionally creative trial designs to test safety and efficacy (with full engagement by FDA).

Best regards, Francis

From: David Liu <[REDACTED]>
Sent: Sunday, April 19, 2020 5:20 PM
To: OD Labc (NIH/OD) <[REDACTED]> Collins, Francis (NIH/OD) [E]
<[REDACTED]>
Cc: Michael Rosbash <[REDACTED]> Ramnik Xavier
<[REDACTED]> EDWARD SCOLNICK <[REDACTED]> Stuart
Schreiber <[REDACTED]> Michael Z Lin <[REDACTED]> Ben
Cravatt <[REDACTED]>
Subject: A proposal to stop COVID-19 and reopen our schools and businesses

Dear Francis,

I hope you are well.

I write on behalf of a group of citizen-scientists, most or all of whom you know. Motivated solely by our desire to help defeat the serious threat our nation and the world now faces, we wrote a set of four actionable, non-partisan proposals (attached) to produce safe and effective COVID-19 therapeutics and vaccines in the shortest possible timeframe, and to reopen our society in a manner that reduces the risk of future COVID-19 outbreaks.

We hope you find these ideas interesting, and might be willing to share this set of proposals with Dr. Tony Fauci, along with our willingness to discuss any part of the proposals with him if we can be helpful. We understand from our efforts to contact Dr. Fauci through email routes that his standard inbox may be too overwhelmed for our proposal to reach him.

The four proposals attached describe: (1) How to rapidly repurpose an antiviral drug to treat COVID-19 patients; (2) How to expedite the development of human antibody drugs to treat patients and to provide short-term protection for healthy individuals, (3) How to develop COVID-19 vaccines on an expedited time scale; and (4) How to reopen our businesses and schools in a manner that reduces the risk of future outbreaks and deaths.

Thank you for any help or thoughts you might be able to provide.

Sincerely yours,

Ben Cravatt (Scripps), Lynn Goldman (GWU), Akiko Iwasaki (Yale), Scott Kemp (MIT), Michael Lin (Stanford), David Liu (Harvard/Broad), Michael Rosbash (Brandeis), Stuart Schreiber (Harvard/Broad), Ed Scolnick (Broad), Jonathan Simons (PCF), and Ramnik Xavier (MGH/Broad)

David R. Liu
Richard Merkin Professor and Director of the Merkin Institute
of Transformative Technologies in Healthcare

APAR0000029005

Director of the Chemical Biology and Therapeutic Sciences Program
Core Institute Member and Vice-Chair of the Faculty, Broad Institute
Investigator, Howard Hughes Medical Institute
Thomas Dudley Cabot Professor of the Natural Sciences
and Professor of Chemistry & Chemical Biology, Harvard University
75 Ames Street
Cambridge, MA 02142

<NIH_ACTIV_Release_041720.docx>

<Scientists_to_Stop_COVID19_2020_04_23_FINAL.pdf>

From: Wood, Gretchen (NIH/OD) [E] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=549F390B39D044A885D1E0E1A8F76C1F-WOODGS]
Sent: 4/6/2020 6:59:05 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]
Subject: Daily COVID-19 PPP calls this week

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Dial-in: | b6
Passcode: b6

Dr. Tabak as Leader: b6

Best wishes,

Gretchen

From: Wood, Gretchen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=549F390B39D044A885D1E0E1A8F76C1F-WOODGS]
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Dr. Tabak as Leader: **b6**

Best wishes,

Gretchen

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Passcode: b6

Dr. Tabak as Leader: b6

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Gretchen

Sent: 4/15/2020 3:13:48 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Washington Post

Maria Freire was not on the any of the previous FNIH list.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 11:01 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Did you look carefully at this list? I didn't see Maria Freire or Larry Tabak. Any others missing?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 10:41 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Francis,

Please see the attached email list. I think this can work for now but I have stressed to FNIH that this is not sufficient long term as the names of who these emails belong to are not listed. Cheryl will further refine but hopefully this will work for now.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 10:01 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Yes this is correct. I also want to ensure that any late additions (reps from BMGF, others) are also captured – we should have the compiled list shortly.

Thanks for your patience – bad timing with 365 updates last night

Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6** >
Sent: Wednesday, April 15, 2020 9:57 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Thanks. I'll wait for the single e-mail list that I can just copy into the bcc line – I assume that's what Cheryl is doing....

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 9:53 AM

To: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Subject: RE: Washington Post

Hi Francis,

We had a few issues this morning -- the FNIH staffer could not open emails due to the 365 update which causes a severe delay.

Here's what just came in -- I've asked Cheryl at FNIH to compile these into a single email list to avoid duplicates and she's doing this now (will have soon). But for the sake of time here are the emails.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, April 15, 2020 9:45 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: RE: Washington Post

Need these in the next 30 minutes -- how is it coming?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, April 15, 2020 8:28 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Myles, Renate (NIH/OD) [E] <[REDACTED]>; Burklow, John (NIH/OD) [E] <[REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>; Freire, Maria (FNIH) [T] <[REDACTED]>; McManus, Ayanna (NIH/OD) [E] <[REDACTED]>
Subject: RE: Washington Post

Good morning Francis et al.

I am working with David to compile the email list -- we will send the list ASAP.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, April 15, 2020 8:10 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Burklow, John (NIH/OD) [E] <[REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]>; Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>; Freire, Maria (FNIH) [T] <[REDACTED]>; McManus, Ayanna (NIH/OD) [E] <[REDACTED]>
Subject: RE: Washington Post

Okay; working it out.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, April 15, 2020 8:02 AM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]>; Burklow, John (NIH/OD) [E] <[REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>

Cc: Wood, Gretchen (NIH/OD) [E] < [REDACTED] b6 Parker, Ashley (NIH/OD) [E] [REDACTED] b6 >;
Wholley, David (FNIH) [T] < [REDACTED] b6 >; Freire, Maria (FNIH) [T] [REDACTED] b6 ; McManus, Ayanna
(NIH/OD) [E] < [REDACTED] b6 >
Subject: RE: Washington Post

Yes, definitely!!! My message to you got caught in the Outlook reboot last night, so when I said "tomorrow" I meant today!

From: Myles, Renate (NIH/OD) [E] [REDACTED] b6
Sent: Wednesday, April 15, 2020 7:35 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 Burklow, John (NIH/OD) [E] [REDACTED] b6 Tabak,
Lawrence (NIH/OD) [E] [REDACTED] b6 Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6
Cc: Wood, Gretchen (NIH/OD) [E] < [REDACTED] b6 Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Wholley, David (FNIH) [T] < [REDACTED] b6 Freire, Maria (FNIH) [T] [REDACTED] b6
Subject: RE: Washington Post

Hi Francis:

Any chance you can speak to Carolyn by end of day today? She's pushing for comment today.

Renate

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Wednesday, April 15, 2020 4:04 AM
To: Myles, Renate (NIH/OD) [E] [REDACTED] b6 >; Burklow, John (NIH/OD) [E] [REDACTED] b6 >; Tabak,
Lawrence (NIH/OD) [E] [REDACTED] b6 Lane, Cliff (NIH/NIAID) [E] < [REDACTED] b6
Cc: Wood, Gretchen (NIH/OD) [E] < [REDACTED] b6 Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Wholley, David (FNIH) [T] < [REDACTED] b6 >; Freire, Maria (FNIH) [T] [REDACTED] b6
Subject: FW: Washington Post

Hi all,

As you can see from Tony's message, he got a green light from WH Comms (Devin O'Malley) for me to talk with Carolyn Johnson tomorrow about ACTIV. Apparently there was no time to discuss this with the Task Force today (they were all focused on economics) but Tony was able to talk with Comms – [REDACTED] b5

[REDACTED] b5 Tony called me earlier in the evening to make sure that wasn't the case, and I reassured him. Given that, the WH Comms said it was OK to talk with Carolyn, [REDACTED] b5

[REDACTED] b5

[REDACTED] b5

Renate, can you work with Gretchen to find a good time for me to talk with Carolyn tomorrow?

I'll need to send out that note to ACTIV partners to let them know a press story is coming. That would include industry, academics, and other government participants. I'm ccing Ashley to ask her to work with David Wholley and his team to get me a complete e-mail list. As you know, Dolsten has agreed to be a press contact. No word back yet from Stoffels.

FC

From: Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]>
Sent: Tuesday, April 14, 2020 9:44 PM
To: Johnson, Carolyn <Carolyn.Johnson@washpost.com>
Cc: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>; Billet, Courtney (NIH/NIAID) [E] <[REDACTED]>; Conrad, Patricia (NIH/NIAID) [E] <[REDACTED]>
Subject: RE: Washington Post

Carolyn:

Thanks for the note. I understand that you will be hearing from Francis Collins on the Public Private Partnership (PPP) that we have put together to combine the resources and assets of industry and the academic community that is largely supported by NIH, particularly NIAID in the context of COVID-19. It is the functional equivalent of a National Strategy. We at NIAID and to some extent other institutes are leveraging our vast clinical trials networks that we built for other infectious diseases, particularly, but not exclusively HIV/AIDS, to provide the capacity to conduct clinical trials (NIH-sponsored as well as industry-sponsored) for both vaccines and therapeutics for COVID-19. For your interest, I am attaching a copy (not yet released) of the NIAID Strategic Plan for COVID-19 Research. It is an outline that will be supplemented with an implementation plan.

Best regards,
Tony

From: Johnson, Carolyn <Carolyn.Johnson@washpost.com>
Sent: Tuesday, April 14, 2020 10:23 AM
To: Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]>
Subject: Washington Post

Dear Tony,

Is there a national strategy at the task force level to coordinate clinical research efforts nationally? We have heard lots of complaints that there isn't a national strategy. I talked to Cliff Lane about this, but we want to give you the chance to respond

Carolyn

Carolyn Johnson
Washington Post
202-334-6248 (desk)
[REDACTED] (cell)

APAR0000029127

Sent: 4/15/2020 2:51:53 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: PLEASE READ: COVID19 Clinical Trials USA and UK
Attachments: Master Sheet COVID-19 IC Participants List and Contract Request v040820.xlsx

We have kept them off for now. We are working on figuring out how FC can send the attached list in email via bcc.

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Wednesday, April 15, 2020 10:50 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Cc: Melencio, Cheryl (FNIH) [T] <[REDACTED]>
Subject: RE: PLEASE READ: COVID19 Clinical Trials USA and UK

Hi Ashley - I honestly don't know. I don't know what Francis wants to tell them and whether he wants them to be on the same list (I am assuming it is sent as a .bcc) or whether he'd want to send them a slightly different side note. You may want to ask him.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, April 15, 2020 10:10 AM
To: Wholley, David (FNIH) [T] <[REDACTED]>
Cc: Melencio, Cheryl (FNIH) [T] <[REDACTED]>
Subject: PLEASE READ: COVID19 Clinical Trials USA and UK

Hi David,

Should the UK partners listed below also be included in the ACTIV master email list Francis will send out today?

Patrick Vallance – Chief Scientist UK
Chris Whitty – Chief Medical Officer UK
Martin Murphy – ACCORD
Ed Whiting – Wellcome
Nick Cammack – Therapeutics Accelerator at Wellcome
Jeremy Farrar – Wellcome

Thanks,
Ashley

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>
Sent: Sunday, April 12, 2020 4:18 PM
To: Jeremy Farrar <[REDACTED]>; Wood, Gretchen (NIH/OD) [E] <[REDACTED]>; Collins, Francis (NIH/OD) [E] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>; Erbelding, Emily (NIH/NIAID) [E] <[REDACTED]>; Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>; Edward Whiting <[REDACTED]>; Nick Cammack <N.Cammack@wellcome.ac.uk>; Whitty, Chris <[REDACTED]>; Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Cc: McManus, Ayanna (NIH/OD) [E] <[REDACTED]>; Simon, Dina (NIH/OD) [C] <[REDACTED]>; Burrus-Shaw, Cyndi (NIH/OD) [E] <[REDACTED]>; Melencio, Cheryl (FNIH) [T] <[REDACTED]>

Carver, Trea (NIH) [C] b6 Lagos, Enrique (NIH/NCATS) [E] < b6
Subject: Re: COVID19 Clinical Trials USA and UK

Thanks Jeremy

Francis Collins – Director, NIH
Larry Tabak – Principal Deputy Director, NIH
Ashley Parker – Special Assistant to Dr. Collins (added to email chain)
Cliff Lane - Deputy Director, Clinical Research and Special Projects, NIAID, NIH
Emily Erbelding – Director, Division of Microbiology and Infectious Diseases, NIAID, NIH
Chris Austin – Director, NCATS, NIH
David Wholley - Senior Vice President of Research Partnerships, Foundation for the NIH (FNIH)
Stacey Adam - Scientific Program Manager for Cancer, FNIH

From: Jeremy Farrar < b6
Date: Sunday, April 12, 2020 at 4:03 PM
To: "Wood, Gretchen (NIH/OD) [E]" < b6 >, Francis Collins < b6 >, "Tabak, Lawrence (NIH/OD) [E]" < b6 "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Adam, Stacey (FNIH) [T]" < b6 "Lane, Cliff (NIH/NIAID) [E]" < b6 "Erbelding, Emily (NIH/NIAID) [E]" < b6 . "Austin, Christopher (NIH/NCATS) [E]" < b6
, Edward Whiting < b6
Nick Cammack < b6 , "Whitty, Chris" < b6
Cc: "McManus, Ayanna (NIH/OD) [E]" < b6 "Simon, Dina (NIH/OD) [C]" < b6 "Burrus-Shaw, Cyndi (NIH/OD) [E]" < b6 "Melencio, Cheryl (FNIH) [T]" < b6 . "Carver, Trea (NIH) [C]" < b6 . "Lagos, Enrique (NIH/NCATS) [E]" < b6
Subject: COVID19 Clinical Trials USA and UK

Francis and colleagues
Best wishes for the Easter Holiday!

Just to link up everyone by email – hope I have not missed anyone off!

Best wishes Jeremy

Patrick Vallance – Chief Scientist UK
Chris Whitty – Chief Medical Officer UK
Martin Murphy – ACCORD
Ed Whiting – Wellcome
Nick Cammack – Therapeutics Accelerator at Wellcome
Jeremy Farrar – Wellcome

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Sent: 4/15/2020 1:51:57 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Washington Post
Attachments: Public Private Collaboration on COVID-19 Distribution List

Hi Francis,

We had a few issues this morning – the FNIH staffer could not open emails due to the 365 update which causes a severe delay.

Here's what just came in – I've asked Cheryl at FNIH to compile these into a single email list to avoid duplicates and she's doing this now. But for the sake of time here is what we have.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 9:45 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Need these in the next 30 minutes – how is it coming?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 8:28 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**; Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**; Burklow, John (NIH/OD) [E] <[REDACTED]> **b6**; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Freire, Maria (FNIH) [T] <[REDACTED]> **b6**; McManus, Ayanna (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Good morning Francis et al.

I am working with David to compile the email list – we will send the list ASAP.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 8:10 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**; Burklow, John (NIH/OD) [E] <[REDACTED]> **b6**; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> **b6**; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Freire, Maria (FNIH) [T] <[REDACTED]> **b6**; McManus, Ayanna (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Okay; working it out.

From: Collins, Francis (NIH/OD) [E] < [REDACTED] > **b6**
Sent: Wednesday, April 15, 2020 8:02 AM
To: Myles, Renate (NIH/OD) [E] [REDACTED] **b6**; Burklow, John (NIH/OD) [E] < [REDACTED] > **b6**; Tabak, Lawrence (NIH/OD) [E] [REDACTED] **b6**; Lane, Cliff (NIH/NIAID) [E] [REDACTED] **b6**
Cc: Wood, Gretchen (NIH/OD) [E] [REDACTED] **b6**; Parker, Ashley (NIH/OD) [E] [REDACTED] **b6**
Wholley, David (FNIH) [T] < [REDACTED] > **b6**; Freire, Maria (FNIH) [T] [REDACTED] **b6** McManus, Ayanna (NIH/OD) [E] [REDACTED] **b6**
Subject: RE: Washington Post

Yes, definitely!!! My message to you got caught in the Outlook reboot last night, so when I said "tomorrow" I meant today!

From: Myles, Renate (NIH/OD) [E] [REDACTED] **b6**
Sent: Wednesday, April 15, 2020 7:35 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] **b6**; Burklow, John (NIH/OD) [E] < [REDACTED] > **b6**; Tabak, Lawrence (NIH/OD) [E] < [REDACTED] > **b6**; Lane, Cliff (NIH/NIAID) [E] < [REDACTED] > **b6**
Cc: Wood, Gretchen (NIH/OD) [E] < [REDACTED] > **b6**; Parker, Ashley (NIH/OD) [E] [REDACTED] **b6**
Wholley, David (FNIH) [T] [REDACTED] **b6**; Freire, Maria (FNIH) [T] [REDACTED] **b6**
Subject: RE: Washington Post

Hi Francis:

Any chance you can speak to Carolyn by end of day today? She's pushing for comment today.

Renate

From: Collins, Francis (NIH/OD) [E] [REDACTED] **b6**
Sent: Wednesday, April 15, 2020 4:04 AM
To: Myles, Renate (NIH/OD) [E] < [REDACTED] > **b6**; Burklow, John (NIH/OD) [E] < [REDACTED] > **b6**; Tabak, Lawrence (NIH/OD) [E] < [REDACTED] > **b6**; Lane, Cliff (NIH/NIAID) [E] < [REDACTED] > **b6**
Cc: Wood, Gretchen (NIH/OD) [E] [REDACTED] **b6**; Parker, Ashley (NIH/OD) [E] [REDACTED] **b6**
Wholley, David (FNIH) [T] [REDACTED] **b6**; Freire, Maria (FNIH) [T] [REDACTED] **b6**
Subject: FW: Washington Post

Hi all,

As you can see from Tony's message, he got a green light from WH Comms (Devin O'Malley) for me to talk with Carolyn Johnson tomorrow about ACTIV. Apparently there was no time to discuss this with the Task Force today (they were all focused on economics) but Tony was able to talk with Comms – [REDACTED] **b5**

[REDACTED] **b5** Tony called me earlier in the evening to make sure that wasn't the case, and I reassured him. Given that, the WH Comms said it was OK to talk with Carolyn, [REDACTED] **b5**

[REDACTED] **b5**

[REDACTED] **b5**

Renate, can you work with Gretchen to find a good time for me to talk with Carolyn tomorrow?

I'll need to send out that note to ACTIV partners to let them know a press story is coming. That would include industry, academics, and other government participants. I'm ccing Ashley to ask her to work with David Wholley and his team to get me a complete e-mail list. As you know, Dolsten has agreed to be a press contact. No word back yet from Stoffels.

FC

From: Fauci, Anthony (NIH/NIAID) [E] b6
Sent: Tuesday, April 14, 2020 9:44 PM
To: Johnson, Carolyn <Carolyn.Johnson@washpost.com>
Cc: Collins, Francis (NIH/OD) [E] b6 Lane, Cliff (NIH/NIAID) [E] b6 >; Billet, Courtney (NIH/NIAID) [E] b6 >; Conrad, Patricia (NIH/NIAID) [E] b6
Subject: RE: Washington Post

Carolyn:

Thanks for the note. I understand that you will be hearing from Francis Collins on the Public Private Partnership (PPP) that we have put together to combine the resources and assets of industry and the academic community that is largely supported by NIH, particularly NIAID in the context of COBID-19. It is the functional equivalent of a National Strategy. We at NIAID and to some extent other institutes are leveraging our vast clinical trials networks that we built for other infectious diseases, particularly, but not exclusively HIV/AIDS, to provide the capacity to conduct clinical trials (NIH-sponsored as well as industry-sponsored) for both vaccines and therapeutics for COVID-19. For your interest, I am attaching a copy (not yet released) of the NIAID Strategic Plan for COVID-19 Research. It is an outline that will be supplemented with an implementation plan.

Best regards,
Tony

From: Johnson, Carolyn <Carolyn.Johnson@washpost.com>
Sent: Tuesday, April 14, 2020 10:23 AM
To: Fauci, Anthony (NIH/NIAID) [E] b6
Subject: Washington Post

Dear Tony,

Is there a national strategy at the task force level to coordinate clinical research efforts nationally? We have heard lots of complaints that there isn't a national strategy. I talked to Cliff Lane about this, but we want to give you the chance to respond.

Carolyn

Carolyn Johnson
Washington Post
202-334-6248 (desk)
b6 (cell)

Name: Public Private Collaboration on COVID-19 Distribution List

Members: Austin, Christopher (NIH/NCATS) [E] (b6
Bright, Rick (b6
Collins, Francis (NIH/OD) [E] (coll b6
Corey, Larry (b6
Disbrow, Gary (OS/ASPR/BARDA) (b6
Dolsten, Mikael (b6
Erbelding, Emily (NIH/NIAID) [E] (b6
Fauci, Anthony (NIH/NIAID) [E] (b6
Frankowski, David (b6
Hudson, Thomas (b6
James, Stephanie (FNIH) [T] (b6
Klock, Kevin (FNIH) [T] (b6)
Lane, Cliff (NIH/NIAID) [E] (b6
Marks, Peter (FDA/CBER) (b6
Marston, Hilary (NIH/NIAID) [E] (b6
Mascola, John (b6
Meeker, David (b6
Menetski, Joseph (FNIH) [T] (b6
Pangalos, Mene (b6
Pao, William (wil b6
Paul, Steve (b6
Perlmutter, Roger (b6
Plump, Andy (b6
Rasi, Gu do (b6
Reed, John (b6
Rouse, Doris (b6
Santos, Michael (FNIH) [T] (b6
Skovronsky, Daniel (b6
Stein, Peter (FDA/CDER) (b6
Stoffels, Paul (b6
Tabak, Lawrence (NIH/OD) [E] (b6
Tsai, John (b6
Vessey, Rupert (b6
Virgin, Skip (b6
Wholley, David (FNIH) [T] (b6
Woodcock, Janet (FDA/CDER) (b6
Young, John (john. b6

From: [REDACTED]
Sent: 2/28/2021 5:01:45 PM
To: Gibbons, Holly (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12ac8daf4a6844bfbbe43bba8774cf5d-gibbonsja]
Subject: Re: For Monday (no need to review/reply this weekend) FW: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Great — thanks, Holly!

Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [REDACTED]

On Feb 28, 2021, at 11:51 AM, Gibbons, Holly (NIH/NCI) [E] <[REDACTED]> wrote:

Hi Ashley,

Sure, happy to share. The response will be addressed to Rep. Cole, and we expect he will pass the information on to the company.

Best,
Holly

Sent from my iPhone

On Feb 28, 2021, at 10:33 AM, Parker, Ashley (NIH/OD) [E] [REDACTED] > wrote:

Thanks, Holly. Could you please share the final response that will be shared with the company? This will be good for us to have in case we are contacted again in the future.

Thanks,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [REDACTED]

On Feb 28, 2021, at 10:13 AM, Gibbons, Holly (NIH/NCI) [E] [REDACTED] wrote:

Thank you, Dr. Parker – we appreciate your follow up as well, especially over the weekend. Hopefully this request was not too much of an interruption!

We will continue to work with Sara and NIAID colleagues as we finalize a response.

Best,
Holly

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Saturday, February 27, 2021 7:44 PM
To: Gibbons, Holly (NIH/NCI) [E] <b6> Selgrade,
Sara (NIH/NIAID) [E] b6
Cc: NCI OGCR <NCIOGCR@mail.nih.gov>; NIAID OCGR Leg
<NIAIDOCGRLeg@mail.nih.gov>; Harris, Kara (NIH/NIAID) [E]
<b6>
Subject: Re: For Monday (no need to review/reply this weekend) FW:
Letter from Rep. Tom Cole re: Princeton based biotech, response due
Wed. 3/3

Good evening,

I'm very thankful for Sara and the information she was able to provide on this inquiry. We received outreach from FNIH and I will let them know NIAID has already been in contact with this company and will provide NCI with the best POC for follow up.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: b6

On Feb 27, 2021, at 1:35 PM, Gibbons, Holly (NIH/NCI) [E]
b6 wrote:

Hi Sara,

Thanks so much for all of this helpful background (and sorry to add to the number of inquiries you have received on this topic!).

We appreciate you and your colleagues confirming the appropriate contact to include in the response. We will plan on sharing our draft response with you on Monday as well, so that you have an opportunity to review.

Enjoy the rest of the weekend,

Holly

From: Selgrade, Sara (NIH/NIAID) [E]
b6
Sent: Saturday, February 27, 2021 1:01 PM
To: Gibbons, Holly (NIH/NCI) [E]
b6 >; Parker, Ashley (NIH/OD) [E]

< [REDACTED] b6

Cc: NCI OGCR <NCIOGCR@mail.nih.gov>; NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>; Harris, Kara (NIH/NIAID) [E] [REDACTED] b6

Subject: RE: For Monday (no need to review/reply this weekend) FW: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Hi Holly,

Thank you for reaching out. We had a recent inquiry from Sen. Lankford's office on behalf of this company (they inquired about a recent meeting the company had with our program staff). Our response below is included for your background.

As you see from the response, unfortunately, there is not much we can do for this company until they identify a partner with vaccine expertise to pair with their proposed adjuvant. We have already provided background information about NIAID funding opportunities and research resources that would be of interest once they do identify such a partner.

My understanding is that the company has received this message already from several of our SMEs. On Monday, we can reach out to see if there is a good contact person for the company to mention in the letter (it may be Dr. Bozick mentioned below).

Thanks,
Sara

NIAID staff regularly conduct meetings with investigators to discuss potential research funding opportunities. As you have noted, Dr. Brooke Bozick, a Program Officer in the Respiratory Diseases Branch of the Division of Microbiology and Infectious Diseases within NIAID, held a discussion with representatives of Sonnet BioTherapeutics, who described their interest in seeking a partnership with the NIAID Vaccine Research Center (VRC) or another vaccine developer to enable evaluation of Sonnet's candidate adjuvant. A collaboration with a vaccine developer is necessary because adjuvants are substances formulated as part of a vaccine to boost immune responses and enhance the vaccine's effectiveness. Dr. Bozick has provided representatives of Sonnet with the

appropriate contacts at the NIAID VRC to explore potential collaborations. It is NIAID's understanding that Sonnet is still in the process of identifying a vaccine developer to partner with for further evaluation of their candidate adjuvant.

Dr. Bozick also described the types of resources NIAID provides to investigators that would be relevant to Sonnet such as the NIAID preclinical services program, which is designed to help decrease the financial risk to product developers by providing critical research resources, including testing in animal models, to fill specific gaps in the product development pipeline. During this discussion, and prior discussions with Sonnet, NIAID staff have outlined the NIH funding opportunities available to the research community for projects on candidate adjuvants.

NIAID welcomes future applications for research resources or research funding from Sonnet should a collaboration with a vaccine developer result in a potential product suitable for evaluation through preclinical testing with NIAID support.

From: Gibbons, Holly (NIH/NCI) [E]

< [REDACTED] b6 >

Sent: Saturday, February 27, 2021 12:30 PM

To: Selgrade, Sara (NIH/NIAID) [E]

[REDACTED] b6 >; Parker, Ashley (NIH/OD) [E]

[REDACTED] b6 >

Cc: NCI OGCR <NCIOGCR@mail.nih.gov>

Subject: For Monday (no need to review/reply this weekend) FW: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Dear Sara and Dr. Parker,

I am reaching out because our NCI Director, Dr. Sharpless, received the attached correspondence from Congressman Tom Cole (R-OK). Rep. Cole is seeking advice to share with a New Jersey-based biotech, Sonnet BioTherapeutics. The company is looking to use an agent that has shown to enhance immune response in the context of cancer immunotherapy (Interleukin-12

delivered through Sonnet's binding platform, more info in the attachment), and combine it with a COVID-19 vaccine in a clinical trial to evaluate the potential to enhance immune response in that context.

We will be providing a brief written response and will encourage Rep. Cole to share contact information for NCI's SBIR program for any future interest the company has in pursuing relevant funding opportunities for their oncology research efforts.

As you will see from the chain below, my colleagues were also trying to identify the most appropriate contact to suggest regarding the company's interest in COVID-19 vaccine research. Our Principal Deputy Director, Dr. Doug Lowy, connected with Dr. Joe Menetski at FNIH to inquire whether ACTIV might be an appropriate venue. Dr. Menetski suggested connecting with you, Dr. Parker, and we of course wanted to keep you in the loop as well, Sara.

We would appreciate any additional guidance you are able to share on Monday, regarding whether there is an appropriate NIAID program colleague that the company could reach out to learn more about any relevant opportunities to submit an application.

Best,
Holly

Holly Aprea Gibbons, MPP
Deputy Director, Office of Government and
Congressional Relations
National Cancer Institute
Direct: b6
Mobile: b6
b6

From: Lowy, Douglas (NIH/NCI) [E]
b6

Sent: Saturday, February 27, 2021 12:04 PM

To: Menetski, Joseph (FNIH) [T] <b6>
Weingarten, Michael (NIH/NCI) [E]

b6 ; Gibbons, Holly (NIH/NCI)
[E] b6 Sharpless, Norman
(NIH/NCI) [E] <b6>

Cc: Lubenow, Anne (NIH/NCI) [E]

<b6> ; Johnson, Maureen
(NIH/NCI) [E] <b6> >; Holohan,
MK (NIH/NCI) [E] b6 >; Freire,
Maria (FNIH) [T] b6 ; Wholley, David

(FNIH) [T] < [b6]

Subject: Re: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Holly: As Joe advises, I suggest you follow-up Ashley Parker. Doug

From: "Lowy, Douglas (NIH/NCI) [E]"

[b6]

Date: Saturday, February 27, 2021 at 12:03 PM

To: "Menetski, Joseph (FNIH) [T]"

[b6]

>, "Weingarten, Michael

(NIH/NCI) [E]" <

[b6]

, "Gibbons, Holly (NIH/NCI) [E]"

<

[b6]

"Sharpless, Norman

(NIH/NCI) [E]"

[b6]

Cc: "Lubenow, Anne (NIH/NCI) [E]"

<

[b6]

. Maureen Johnson

[b6]

>, "Holohan, MK

(NIH/NCI) [E]"

[b6]

, "Freire,

Maria (FNIH) [T]" <

[b6]

, "Wholley,

David (FNIH) [T]"

[b6]

>

Subject: Re: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Joe: Many thanks! Doug

From: "Menetski, Joseph (FNIH) [T]"

<

[b6]

Date: Saturday, February 27, 2021 at 11:25 AM

To: "Lowy, Douglas (NIH/NCI) [E]"

<

[b6]

"Weingarten, Michael

(NIH/NCI) [E]" <

[b6]

, "Gibbons, Holly (NIH/NCI) [E]"

[b6]

>, "Sharpless, Norman

(NIH/NCI) [E]" <

[b6]

Cc: "Lubenow, Anne (NIH/NCI) [E]"

<

[b6]

. Maureen Johnson

<

[b6]

"Holohan, MK

(NIH/NCI) [E]" <

[b6]

>, "Freire,

Maria (FNIH) [T]" <

[b6]

"Wholley,

David (FNIH) [T]" <

[b6]

Subject: RE: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Dear Doug,

Thank you for the note. Adding an immune activator to a vaccine to increase efficacy and immunogenicity

sounds like an interesting approach. ACTIV has received one or two submissions to the asset portal with similar suggestions, but not using IL-12. As you probably know, ACTIV has not been focusing on this type of vaccine support, so in the past we have shared these submissions directly with the NIAID colleagues so they could assess the fit for their efforts.

Given that this has come through a member of congress, I would suggest having the company contact Dr. Ashley Parker in OD to ensure that this is addressed by the appropriate group in NIAID. Ashley and the NIAID group can assess how best to follow up with the potential vaccine approach.

Best regards,
Joe

From: Lowy, Douglas (NIH/NCI) [E]

< [REDACTED] b6 >

Sent: Friday, February 26, 2021 5:43 PM

To: Weingarten, Michael (NIH/NCI) [E]

[REDACTED] b6 ; Gibbons, Holly (NIH/NCI) [E] [REDACTED] b6 Sharpless, Norman

(NIH/NCI) [E] [REDACTED] b6

Cc: Lubenow, Anne (NIH/NCI) [E]

< [REDACTED] b6 > Johnson, Maureen

(NIH/NCI) [E] < [REDACTED] b6 > Holohan,

MK (NIH/NCI) [E] < [REDACTED] b6 > Menetski,

Joseph (FNIH) [T] < [REDACTED] b6 >

Subject: Re: Letter from Rep. Tom Cole re: Princeton-based biotech, response due Wed. 3/3

Holly and Ned,

To me, the next step for the company's proposed approach would be to evaluate it in an experimental model of infection/disease, preferably one for SARS-CoV-2. I'll write to Joe Menetski at FNIH, who is helping to coordinate the ACTIV preclinical working group, and see what he replies.

Thanks,
Doug

Sent: 4/15/2020 12:37:31 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: email list

Francis is requesting this list ASAP – within the next hour or so. Cheryl – if I can be helpful

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 8:22 AM
To: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]> Melencio, Cheryl (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Subject: RE: email list

Good morning and thanks David.

Cheryl is combining the attached ACTIV leadership list (+ Skovronsky and Hudson), the WG master list (2nd attachment – emails needed), and the heads of R&D who participated in the April 3rd call if not listed on the WG roster (last attachment – emails needed), + Dolsten, right?

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]
Sent: Wednesday, April 15, 2020 7:37 AM
To: Melencio, Cheryl (FNIH) [T] [REDACTED] b6 [REDACTED]
Cc: Parker, Ashley (NIH/OD) [E] [REDACTED]
Subject: RE: email list

Oops, pushed send too soon: Please send these lists to Ashley Parker at NIH (copied). This is pretty urgent. Thanks

From: Wholley, David (FNIH) [T]
Sent: Wednesday, April 15, 2020 7:36 AM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Cc: Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED] v>
Subject: email list

Cheryl, can you please pull together an email list (or lists) that includes all of our partners—the expanded list of the ACTIV Leadership Team that now includes Skovronsky and Hudson, and the lists of all of the WGs.

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

[REDACTED] b6 [REDACTED]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Sent: 5/14/2020 10:24:04 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: email list
Attachments: FNIH Covid Team List 040820 vF2.docx; COVID Working Group Rosters - MASTER.pdf; Agenda-Discussion Guide for Introductory COVID final.docx

Thanks, David.

Cheryl is combining the attached ACTIV leadership list (+ Skovronsky and Hudson), the WG master list (2nd attachment – emails needed), and the heads of R&D who participated in the April 3rd call if not listed on the WG roster (last attachment – emails needed), + Dolsten right?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 7:37 AM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: email list

Oops, pushed send too soon: Please send these lists to Ashley Parker at NIH (copied). This is pretty urgent. Thanks

From: Wholley, David (FNIH) [T]
Sent: Wednesday, April 15, 2020 7:36 AM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: email list

Cheryl, can you please pull together an email list (or lists) that includes all of our partners—the expanded list of the ACTIV Leadership Team that now includes Skovronsky and Hudson, and the lists of all of the WGs.

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Sent: 4/22/2020 8:50:59 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: ACTIV email?

FYI – you may be OK with this but I thought we should hold off on developing a central inbox for ACTIV until we see what happens with the portal in development. If the WG's want to use an inbox for outside submissions info seems having one centralized place would be useful

From: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, April 22, 2020 4:44 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6** Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** James, Stephanie (FNIH) [T] <[REDACTED]> **b6** Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6** Santos, Michael (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: ACTIV email?

I need a place where we can ask people to upload additional information that will be included with our survey results – I leave the mechanics of how we obtain that information up to the experts

Others can chime in if they think a general mailbox for the partnership would be useful.

Many thanks!
Karen

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, April 22, 2020 4:30 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** , Tountas, Karen (FNIH) [T] <[REDACTED]> **b6** Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** ; James, Stephanie (FNIH) [T] <[REDACTED]> **b6** Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6** ; Santos, Michael (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: ACTIV email?

Sure. Karen, the purpose of this email address is not to act as the reply to box for the survey, is it? But it would collect additional info specifically for that survey? Or as a general mailbox for the partnership? This will be important to understand.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 22, 2020 4:24 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6** Tountas, Karen (FNIH) [T] <[REDACTED]> **b6** ; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** ; James, Stephanie (FNIH) [T] <[REDACTED]> **b6** Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6** ; Santos, Michael (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: ACTIV email?

Hi David et al.,

David, could we discuss more broadly with the group tomorrow during our war room call? I am afraid we have several moving parts with the online portal in development. May I suggest while NIH is in the process of building the portal for ACTIV queries/submissions – we consider adding this component for network/site information? If this seems reasonable to the FNIH team – we could discuss tomorrow and connect Karen with the NIH staff collecting information for building the portal.

I am not opposed to having a central email but I think this is one purpose of having the online portal – thoughts?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Wednesday, April 22, 2020 4:01 PM
To: Tountas, Karen (FNIH) [T] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; James, Stephanie (FNIH) [T] <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>; Santos, Michael (FNIH) [T] <[REDACTED]>
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: RE: ACTIV email?

Yes it makes sense with me but since ACTIV was coined by NIH, I will check this now with Ashley Parker before we move forward. Thanks, David

From: Tountas, Karen (FNIH) [T] <[REDACTED]>
Sent: Wednesday, April 22, 2020 2:00 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]>; James, Stephanie (FNIH) [T] <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>; Santos, Michael (FNIH) [T] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>
Subject: ACTIV email?

Colleagues,

While we were editing the survey with David Goff today, we talked about the utility of having an ACTIV specific email address ACTIV@fnihi.org? The Survey subgroup would use this to obtain additional network/site information that cannot be addressed through the survey – e.g., the network's roster of sites. We discussed that it might be better to have a 'general' ACTIV email address versus using a specific person's email. I like this idea – would this be of use to any of you? David, would this be acceptable?

Many thanks, in advance, for your thoughts.
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
[REDACTED] | fnihi.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Stay at the forefront of FNIH news: fnihi.org/newsletter

Confidentiality Notice: This email and any files transmitted with it are confidential and intended solely for the individual named. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system.

Sent: 4/17/2020 3:59:51 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv 041720
Attachments: Master and WG Email List for ACTIV rv 041720.xlsx

Hopefully my last version for today -- this one has Maria added to the master list and the two Gmail accounts are accounted for.

Thanks,
Ashley

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, April 17, 2020 10:26 AM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Subject: RE: Emailing: Master and WG Email List for ACTIV rv 041720

I forgot to ask -- can we identify what companies these two reps below work for? We currently only have their personal Gmail accounts.

Fernandes, Prabhavathi <[REDACTED]> b6 Gottesdiener, Keith <[REDACTED]> b6

Thanks,
Ashley

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, April 17, 2020 10:17 AM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Subject: RE: Emailing: Master and WG Email List for ACTIV rv 041720

Thanks Cheryl!

Please save the attached version -- Rao, Srinivas <[REDACTED]> b6 was added to the industry/private list but inadvertently left off of the master list. I have included his email in the master list -- we will need to ensure we include any additions to the master list as well.

Keeping track of these will certainly ensure we are ready for the next email request!

Have a great Friday and weekend!

Ashley

-----Original Message-----

From: Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Sent: Friday, April 17, 2020 9:34 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: Emailing: Master and WG Email List for ACTIV rv 041720

Hi Ashley, Here is updated copy as of this morning. I will add the current date in the file name when I update it.

Have a good Friday!

Cheryl

Your message is ready to be sent with the following file or link attachments:

Master and WG Email List for ACTIV rv 041720

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

Sent: 4/17/2020 2:26:09 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv 041720
Attachments: Master and WG Email List for ACTIV rv 041720.xlsx

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Fernandes, Prabhavathi <[REDACTED]> b6
Gottesdiener, Keith <[REDACTED]> b6

Thanks,
Ashley

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, April 17, 2020 10:17 AM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Subject: RE: Emailing: Master and WG Email List for ACTIV rv 041720

Thanks Cheryl!

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From: Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Sent: Friday, April 17, 2020 9:34 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: Emailing: Master and WG Email List for ACTIV rv 041720

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Cheryl

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Master and WG Email List for ACTIV rv 041720

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Sent: 4/17/2020 2:13:15 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv 041720
Attachments: Master and WG Email List for ACTIV rv 041720.xlsx

Thanks Cheryl!

Please save the attached version --

-----Original Message-----

From: Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Sent: Friday, April 17, 2020 9:34 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: Emailing: Master and WG Email List for ACTIV rv 041720

Hi Ashley, Here is updated copy as of this morning. I will add the current date in the file name when I update it.

Have a good Friday!

Cheryl

Your message is ready to be sent with the following file or link attachments:

Master and WG Email List for ACTIV rv 041720

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

From: Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Sent: 3/2/2021 2:20:39 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]

Subject: Accepted: ACTIV Vaccines Working Group meeting

Location: <https://nih.zoomgov.> **b6**

Start: 3/3/2021 5:00:00 PM

End: 3/3/2021 6:00:00 PM

Show Time As. Busy

From: Gadbois, Elen (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Sent: 3/1/2021 3:19:51 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Accepted: ACTIV Vaccines Working Group meeting
Location: <https://nih.zoomgov.com/> **b6**
Start: 3/3/2021 4:30:00 PM
End: 3/3/2021 5:30:00 PM
Show Time As. Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 3/4/2021 1:59:15 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]
Subject: RE: conversation on 2 policy issues in ACTIV

Right. I think you should just tell Joe what to say to the ACTIV folks.

From: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, March 4, 2021 8:15 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: conversation on 2 policy issues in ACTIV

Hi Ellen,

I'm not entirely sure what this discussion will entail, and I can just listen to what FNIH is asking for and respond accordingly, but these policy issues are already being handled by OSP. We are addressing any individual questions about what constitutes a Major Action, when they arise, and we had a specific discussion with Sheri Hild about the process for requesting containment lowering. Basically, the answer is, if those questions come up, send them to us (which I think is what I have said before...)

Thanks,

Jessica

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] **b6**
Sent: Wednesday, March 3, 2021 1:15 PM
To: Tucker, Jessica (NIH/OD) [E] [REDACTED] **b6**
Cc: Menetski, Joseph (FNIH) [T] [REDACTED] **b6**; Culp, Michelle (NIH/OD) [E] [REDACTED] **b6**; Letts, Kinshasa (NIH/OD) [C] [REDACTED] **b6** >
Subject: conversation on 2 policy issues in ACTIV

Hi Jessica,

I was just on a call with the FNIH folks working on ACTIV and Joe Menetski (cc'd here) noted that there are 2 recurring topics in the ACTIV preclinical working group that are NIH policy issues. Joe would like to find a way to move them out of the ongoing ACTIV conversations. I thought the best next step is for you and Joe to talk—I'm happy to be on and am copying Michelle in case she can join. As we've all talked about before, there are things related to the emerging variants. Second, there is also discussion about moving animals from BSL3 to BLS2. Hopefully Kinshasa can help us find some time together.
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: [REDACTED] b6
fax: 301-402-0280

GADB0000000065



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Running Discovery Into Health

From: Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Sent: 3/3/2021 8:35:29 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV FNIH/Deloitte Touchbase
Location: see webex below

Start: 3/10/2021 5:30:00 PM
End: 3/10/2021 6:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Sent: 3/3/2021 8:35:23 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV FNIH/Deloitte Touchbase
Location: see webex below

Start: 3/12/2021 7:00:00 PM
End: 3/12/2021 7:30:00 PM
Show Time As. Busy

From: Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Sent: 3/3/2021 8:35:15 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV FNIH/Deloitte Touchbase
Location: see webex below

Start: 3/17/2021 6:00:00 PM
End: 3/17/2021 6:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Sent: 3/3/2021 8:35:05 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV FNIH/Deloitte touchbase
Location: see webex below
Start: 3/19/2021 5:00:00 PM
End: 3/19/2021 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 1/12/2021 6:31:01 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Deloitte & FNIH Touchbase
Location: see webex below
Start: 1/15/2021 9:00:00 PM
End: 1/15/2021 9:30:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 1/11/2021 8:49:15 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: January ACTIV Pre-call

David didn't say.

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]>
Sent: Monday, January 11, 2021 3:44 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Subject: RE: January ACTIV Pre-call

Is that about TransCelerate providing a contacts for enrollment sites?

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Monday, January 11, 2021 1:38 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]>
Subject: RE: January ACTIV Pre-call

FYI they are going to say something during the real call that Transcelerate has done what ACTIV has asked.

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]>
Sent: Monday, January 11, 2021 12:30 PM
To: Wholley, David (FNIH) [T] <[REDACTED]>
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> Menetski, Joseph (FNIH) [T] <[REDACTED]>
Subject: RE: January ACTIV Pre-call

David,
I have a conflict today and won't be able to join.
Best,
Michelle

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Monday, January 11, 2021 11:53 AM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>; Collins, Francis (NIH/OD) [E] <[REDACTED]>; Culp, Michelle (NIH/OD) [E] <[REDACTED]>; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Margaret Anderson <[REDACTED]>; Appell, Evan <[REDACTED]>; Chen, Helen <[REDACTED]>; Connelly, Sarah <[REDACTED]>; Gonzalez, Nina <[REDACTED]>; Hawk, Harrison <[REDACTED]>; Mendelson, Jesse <[REDACTED]>; Nasr, Hana <[REDACTED]>; Santos, Michael (FNIH) [T] <[REDACTED]>; Sorosa, Alex <[REDACTED]>; Stratton, Benjamin <[REDACTED]>; btolman <[REDACTED]>; Tountas, Karen (FNIH) [T] <[REDACTED]>; Wachtel, Jonathan <[REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]>; McManus, Ayanna (NIH/OD) [E] <[REDACTED]>; Simon, Dina (NIH/OD) [C] <[REDACTED]>; Burrus-Shaw, Cyndi (NIH/OD) [E] <[REDACTED]>
Subject: RE: January ACTIV Pre-call

All: here are slides for our EC/LT pre-call at 1PM today. Thanks, David

From: Gadbois, Elen (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 1/6/2021 3:41:31 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below

Start: 1/8/2021 4:30:00 PM
End: 1/8/2021 5:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/30/2020 1:47:00 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Young, Cari (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7765319e02c347ed8466c56e5ae61be5-youngce]
Subject: Fwd: questions from Chairman Johnson for FC on ACTIV
Attachments: image001.png; Johnson response NCATS final[1].docx

FYI Chris Everett is OLPA POC on this now for rest of week. Looks like NCATS (and earlier NHLBI) have responded but not yet NIAID. And my massaging of FNIH responses is below.

Sent from my iPhone

Begin forwarded message:

From: "Lohmann, Larry (NIH/OD) [E]" <[REDACTED] b6>
Date: December 30, 2020 at 6:27:02 AM EST
To: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED] b6>
Cc: "Culp, Michelle (NIH/OD) [E]" <[REDACTED] b6> "Brodd, Lauren (NIH/OD) [E]" <[REDACTED] b6> "Everett, Chris (NIH/OD) [E]" <[REDACTED] b6>
Subject: Re: questions from Chairman Johnson for FC on ACTIV

Good morning,

Today it is my turn to disappear for a few days. Attached is the contribution from NCATS, just for reference. Please note Chris Everett is cc'd here and will be the POC for this issue in OLPA while I am out. We are still waiting on NIAID. I spoke to Chase Crawford yesterday, that may come as soon as today.

Very respectfully,
Larry

From: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED] b6>
Date: Saturday, December 26, 2020 at 9:08 PM
To: "Lohmann, Larry (NIH/OD) [E]" <[REDACTED] b6>
Cc: "Culp, Michelle (NIH/OD) [E]" <[REDACTED] b6> "Brodd, Lauren (NIH/OD) [E]" <[REDACTED] b6>
Subject: FW: questions from Chairman Johnson for FC on ACTIV

Hi Larry,

Tomorrow morning I am heading to a cabin with no cell signal. I'll be back in town Wednesday Dec 30 and still on leave, so I will just check email a few times. I think David gave reasonable answers to questions 1 and 3 below. I would just of course take out the

sentence about listing every drug—I think it would be fair to wait and see if Senator Johnson really wants more details on the repurposed drugs (beyond ivermectin, and I don't know the story there).

So far 've only seen a response to Q2 back from NHLBI, which I forwarded to you. I put Michelle Culp on my out of office message (sorry Michelle) so hopefully if N AID and NCATS don't respond to you directly, Michelle could forward them.

Hope this works out without too much fuss.

Ellen

1) What repurposed drugs have been investigated?

ACTIV has reviewed over 500 different potential drugs for COVID-19. We have approached this from the standpoint of what are the most promising drugs?, regardless of whether or not they are repurposed or novel per se. However, of course there are many more existing drugs for other indications out there that can be repurposed than there are novel drugs in development, so the preponderance of what we've looked at is in the repurposed category—80% would not be an unreasonable estimate. ~~If the Senator really wants a list of every drug that was considered separated out by repurposed vs. novel I suppose we could do that, but it would take some time.~~ Of the drugs listed on slide 8 in the deck we sent to Ashley, all of the drugs are repurposed except the neutralizing antibodies mentioned in connection with ACTIV-2 and ACTIV-3.

2) ~~How much money has been spent studying existing drugs?~~

~~This is a question for NIH of course.~~

3) Who/what is the group that has been reviewing them?

The ACTIV Agent Prioritization team consists of about 40 experts in the field with knowledge of and broad experience in both basic science and drug development. About 50% are from various federal agencies, 25% from academic research institution, and 25% from industry. They are broken down into three subteams with specific expertise in antivirals, immune modulators, and symptomatic/supportive drugs (such as anticoagulants). The evaluations performed by the subteam are further reviewed with the entire Agent Prioritization team before being forwarded to the trial teams at the NIH. NIH, as the sponsor of the ACTIV trials, makes the final decision regarding which get tested.

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Wednesday, December 23, 2020 11:31 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED]>
Menetski, Joseph (FNIH) [T] <[REDACTED]> Gonzalez, Nina <[REDACTED]> Chen,
He en <[REDACTED]>
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> Culp, Michelle (NIH/OD) [E]
<[REDACTED]> Brodd, Lauren (NIH/OD) [E] <[REDACTED]> Lohmann, Larry
(NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Appell, Evan
<[REDACTED]>
Subject: RE: questions from Chairman Johnson for FC on ACTIV
Importance: High

Please see answers in italics below. I hope this is sufficiently comprehensive.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Wednesday, December 23, 2020 10:37 AM
To: Wholley, David (FNIH) [T] b6 >; Adam, Stacey (FNIH) [T] b6 ,
Menetski, Joseph (FNIH) [T] < b6 Gonzalez, Nina < b6 Chen,
Helen b6 >
Cc: Parker, Ashley (NIH/OD) [E] b6 >; Culp, Michelle (NIH/OD) [E]
b6 Brodd, Lauren (NIH/OD) [E] b6 ; Lohmann, Larry
(NIH/OD) [E] b6
Subject: questions from Chairman Johnson for FC on ACTIV

Dear FNIH and Deloitte folks,

I am really sorry to be asking this as I know Stacey is on well-deserved leave and I'm sure others are trying to wrap up work. But...Dr. Collins spoke to Chairman Ron Johnson yesterday and the Chairman had follow-up questions, specifically regarding repurposed drugs. The Chairman already has the attached slide set, which Ashley provided. (Slides 5-7 focus on the number and category of agents submitted/reviewed by ACTIV to date, but it doesn't break out repurposed drugs.)

With regards to repurposing drugs only for ACTIV:

1) What repurposed drugs have been investigated?

ACTIV has reviewed over 500 different potential drugs for COVID-19. We have approached this from the standpoint of what are the most promising drugs?, regardless of whether or not they are repurposed or novel per se. However, of course there are many more existing drugs for other indications out there that can be repurposed than there are novel drugs in development, so the preponderance of what we've looked at is in the repurposed category—80% would not be an unreasonable estimate. If the Senator really wants a list of every drug that was considered separated out by repurposed vs. novel I suppose we could do that, but it would take some time. Of the drugs listed on slide 8 in the deck we sent to Ashley, all of the drugs are repurposed except the neutralizing antibodies mentioned in connection with ACTIV-2 and ACTIV-3.

2) How much money has been spent studying existing drugs?

This is a question for NIH of course.

3) Who/what is the group that has been reviewing them?

The ACTIV Agent Prioritization team consists of about 40 experts in the field with knowledge of and broad experience in both basic science and drug development. About 50% are from various federal agencies, 25% from academic research institution, and 25% from industry. They are broken down into three subteams with specific expertise in antivirals, immune modulators, and symptomatic/supportive drugs (such as anticoagulants). The evaluations performed by the subteam are further reviewed with the entire Agent Prioritization team before being forwarded to the trial teams at the NIH. NIH, as the sponsor of the ACTIV trials, makes the final decision regarding which get tested.

I'm hoping you can answer question #1 and #3. (For #3, I'm just not sure what is the formal name of the agent prioritization groups and how you describe them.)

For question #2...I don't expect that you have that information, but if you have any thoughts on who I should check with to come up with some kind of answer, I'd appreciate it.

I'm copying Larry Lohmann, a colleague in NIH's legal affairs shop, to expedite getting a response together.

Thanks very much.

Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Gadbois, Elen (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/22/2020 4:47:34 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]
Subject: Accepted: ACTIV Preclinical full working group
Location: <https://fnih.zoom>. **b6**
Start: 4/22/2020 2:00:00 PM
End: 4/22/2020 3:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/23/2020 3:18:06 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Ivermectin

FYI I hate to flag stuff for you but just FYI I have questions that Sen. Johnson asked FC yesterday about repurposed candidates. I need a few minutes to get that email organized. Hopefully Deloitte folks can get that data together and not you, but wanted you to be aware.

From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Wednesday, December 23, 2020 10:15 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> Brodd, Lauren (NIH/OD) [E] <[REDACTED]>
Subject: RE: Ivermectin

Hi Ellen,

Yes, that is what I was going to send. I got the impression from Ashley that that was meant to be the standard response to all external queries on Ivermectin.

I will take another look at Michelle's email.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] Mobile: [REDACTED]

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED]
Sent: Wednesday, December 23, 2020 10:05 AM
To: Adam, Stacey (FNIH) [T] [REDACTED]
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> Brodd, Lauren (NIH/OD) [E] [REDACTED]
Subject: FW: Ivermectin

Stacey we do have this from Ashley, in case that's what you were looking to send.

From: Parker, Ashley (NIH/OD) [E] [REDACTED]
Sent: Monday, December 21, 2020 4:34 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]>
Cc: Wholley, David (FNIH) [T] <[REDACTED]>; Gadbois, Ellen (NIH/OD) [E] [REDACTED]; Brodd, Lauren (NIH/OD) [E] [REDACTED]
Subject: RE: Ivermectin

Hi Stacey,

Our ES prepared the attached response to several incoming inquiries about the evaluation of Ivermectin. This draft was based on prior email exchange but I remember hearing the decision was made to not move forward but possibly re-evaluate the compound with a different team.

I wanted to confirm, do we want to convey the decision was made to not move forward with Ivermectin at this time or share the ACTIV team is currently in the process of reevaluating ivermectin based on new data?

FYI – b6 in case you receive any inquiries between now and then from Ellen G. or Lauren Brodd in OD.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] b6 >
Sent: Wednesday, December 16, 2020 8:22 AM
To: Collins, Francis (NIH/OD) [E] b6 >, Adam, Stacey (FNIH) [T] b6 >; Parker, Ashley (NIH/OD) [E] b6 >
Cc: Hallett, Adrienne (NIH/OD) [E] b6 >; Freire, Maria (FNIH) [T] < b6 >
Subject: RE: Ivermectin

Ivermectin is being reviewed by the Agent Prioritization Antiviral Subteam at about 4pm this afternoon.

From: Collins, Francis (NIH/OD) [E] b6
Sent: Wednesday, December 16, 2020 6:54 AM
To: Wholley, David (FNIH) [T] < b6 >; Adam, Stacey (FNIH) [T] b6 >; Parker, Ashley (NIH/OD) [E] <a b6 >
Cc: Hallett, Adrienne (NIH/OD) [E] b6
Subject: Ivermectin

Anything new in the prioritization re-review of ivermectin? Getting some pressure from a couple of Senators....

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/21/2020 9:00:32 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: I'm still on another call...

You too, Michelle! Hope you got testing sorted out and no one's out in a tent.

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, December 21, 2020 3:38 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: I'm still on another call...

Ellen,
Thanks for the updates!
I hope you and your family have a nice holiday!
Best,
Michelle

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, December 21, 2020 2:34 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: I'm still on another call...

The main topic was discussion about the variant spreading in the UK. Lilly and Regeneron say that it shouldn't affect efficacy of their mAbs. **b5**

ACTIV 4a is being paused—Amy Patterson said this is close hold but apparently it's already on Twitter. (I think David said because of futility in the critically ill—I'm not sure I heard "futility" correctly.)

Finally there is some discussion of whether ACTIV 2 can help an already ongoing trial of fluvoxacin. The PI, Eric Lensey, said he could use help with accrual. FC wanted to see if there was something ACTIV 2 could do to help. Stacy said that ACTIV 2 has already hit capacity for agents unless there is more funding. David is looking into what's going on with another funding request that might be underway. Steve Kirsch, who developed the optical mouse, is pushing this.

Not more check-ins of this group till Jan ②

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, December 21, 2020 2:04 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6** >; Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6** Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** >
Subject: I'm still on another call...

...and will be late to the ACTIV-FNIH call.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/23/2020 3:00:18 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: TIME SENSITIVE RESPONSE: ivermectin

Sorry I have been on a call. Let me look—I saw something on this.

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, December 23, 2020 9:52 AM
To: Chen, Helen <[REDACTED]> **b6** Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6** Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: TIME SENSITIVE RESPONSE: ivermectin
Importance: High

Dear Joe and Helen,
I'm hoping you can help me this morning/ASAP. I see Stacey is out, so I'm ccing her as FYI.
NIH is responding to an inquiry about ivermectin and its agent prioritization outcome. I need your assistance in reviewing the paragraph below.

"The ACTIV team recently completed a reevaluation of ivermectin and, again, has determined that the current data provided for evaluation does not provide strong enough evidence to move forward at this time. The team will continue to track any forthcoming information and will reevaluate if new information becomes available. NIH is committed to funding the most promising research to advance our ability to treat and prevent COVID-19 with the resources available to us."

It was suggested we add more detail about the reevaluation and why the decision was made. **What detail about the evaluation and decision was provided to the company?** Can you provide any more information, or a "for example...." that would be aligned with the direction of the agent prioritization process?

Many thanks!
-Michelle

From: Hewitt, Judith (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D0A7DADFCBD42CBB4014D9B26AF30CC-JHEWITT]
Sent: 12/15/2020 11:12:35 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: FW: Latest BSL 3-4 Inventory
Attachments: Copy of ACTIV PRECLINICAL_BSL 3 - 4 Inventory 20200804-1AH.xlsx; NIAID Contracting Pools.xlsx

Hi Ellen,
I went back to find who was collecting what info, and here's part of that trail, the part where I shared info.
Happy to talk if we need to,
Judy

From: Hewitt, Judith (NIH/NIAID) [E]
Sent: Tuesday, August 11, 2020 2:35 PM
To: Alvarez, Rosa Maria <[REDACTED]> b6
Cc: Ottinger, Elizabeth (NIH/NCATS) [E] <[REDACTED]> b6 Menetski, Joseph (FNIH) [T] <[REDACTED]> b6
Hawk, Harrison <[REDACTED]> b6
Subject: RE: Latest BSL 3-4 Inventory

Sorry for the delay, I'm trying to be somewhat on leave this week.

Attached are

- Your file with my updates in red. I noticed some things missing so I'm also giving you..
- A list of our contract pools, all of the animal models and just the viral part of in vitro. Note that we have a couple of contracts outside of this pool, like one to Sarah Cherry/U Penn, that we were able to quickly execute due to COVID, but I'm not sure we can do it again as quickly.
- BARDA's non-clinical network contractors are here:
https://www.medicalcountermeasures.gov/media/36/55/2014_05_13_bar_da_core_serv_ices_amn_map.pdf

Hope this helps!
Judy

From: Alvarez, Rosa Maria <[REDACTED]> b6 >
Sent: Sunday, August 9, 2020 10:55 PM
To: Hewitt, Judith (NIH/NIAID) [E] <[REDACTED]> b6
Cc: Ottinger, Elizabeth (NIH/NCATS) [E] <[REDACTED]> b6 Menetski, Joseph (FNIH) [T] <[REDACTED]> b6 >;
Hawk, Harrison <[REDACTED]> b6
Subject: RE: Latest BSL 3-4 Inventory

Hi Judy,

Hope all is well. Wanted to follow-up on the email below. Could you take a look at our latest inventory and provide feedback where needed? Also, I believe you had asked someone in your team to share sites that have organoid/3D tissue culture systems – if you have that information please let us know.

Regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile, [REDACTED] b6

GADB0000000199

From: Alvarez, Rosa Maria
Sent: Tuesday, August 4, 2020 12:09 PM
To: Hewitt, Judith (NIH/NIAID) [E] b6
Cc: Ottinger, Elizabeth (NIH/NCATS) [E] < b6 >; Menetski, Joseph (FNIH) [T] b6 >; Hawk, Harrison b6 >
Subject: Latest BSL 3-4 Inventory

Hi Judy,

Please see attached for the latest BSL 3-4 site inventory. I believe you had asked someone in your team to share sites that have organoid/3D tissue culture systems – if you have that information please let us know.

Thanks for your time and help,

Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: b6
www.deloitte.com

This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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From: Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Sent: 2/26/2021 6:08:36 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV Pre-call
Location: see webex below

Start: 3/15/2021 6:00:00 PM
End: 3/15/2021 6:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/11/2020 7:47:15 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below

Start: 1/8/2021 6:00:00 PM
End: 1/8/2021 6:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/30/2020 4:10:45 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 12/9/2020 5:00:00 PM
End: 12/9/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/30/2020 4:10:32 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below

Start: 12/11/2020 7:30:00 PM
End: 12/11/2020 8:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/30/2020 4:05:04 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Call
Location: see webex below
Start: 12/2/2020 7:00:00 PM
End: 12/2/2020 7:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/11/2020 7:47:05 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 1/6/2021 5:00:00 PM
End: 1/6/2021 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/30/2020 4:04:56 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Call
Location: see webex below
Start: 12/4/2020 8:00:00 PM
End: 12/4/2020 8:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/11/2020 7:46:58 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 12/21/2020 7:00:00 PM
End: 12/21/2020 7:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/11/2020 7:46:52 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 12/18/2020 4:30:00 PM
End: 12/18/2020 5:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/17/2020 11:36:47 AM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]
Subject: Re: Text from Baric chat

Guess you get to facilitate! Next time you can tell me about it.
The ACTIV group has a call tomorrow so glad you got the story straight with FNIH now.

Sent from my iPhone

On Nov 16, 2020, at 3:49 PM, Tucker, Jessica (NIH/OD) [E] <[REDACTED]> wrote.

Sure. This is utterly bizarre. UNC needs to communicate internally.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Monday, November 16, 2020 3:48 PM
To: Tucker, Jessica (NIH/OD) [E] <[REDACTED]>
Subject: RE: Text from Baric chat

Just FYI in case Joe wants to talk this afternoon--I have to run an errand now but you should feel free to go ahead without me. Joe is very nice.

From: Tucker, Jessica (NIH/OD) [E] <[REDACTED]>
Sent: Monday, November 16, 2020 3:47 PM
To: Menetski, Joseph (FNIH) [T] <[REDACTED]>; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]>; Melencio, Cheryl (FNIH) [T] <cmel@fnih.gov>
Subject: RE: Text from Baric chat

Yes. I am free now until 5 PM, or tomorrow 12- 1 or 3:30-5 PM.

Thanks,

Jessica

From: Menetski, Joseph (FNIH) [T] <[REDACTED]>
Sent: Monday, November 16, 2020 3:46 PM
To: Tucker, Jessica (NIH/OD) [E] <[REDACTED]>; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]>; Melencio, Cheryl (FNIH) [T] <[REDACTED]>
Subject: RE: Text from Baric chat

Hi Jessica,

Thank you for the quick response. I think a short phone call would be a good idea.

Would you be able to get on a quick call in the next day or so?

Best,
Joe

From: Tucker, Jessica (NIH/OD) [E] <j[REDACTED] b6
Sent: Monday, November 16, 2020 3:37 PM
To: Menetski, Joseph (FNIH) [T] <jm[REDACTED] b6 Gadbois, Ellen (NIH/OD) [E]
<[REDACTED] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: Text from Baric chat

Hi Joe,

Yes, the relevant institutional official (the biosafety officer) at UNC reached out to us a few weeks ago and we had a call with him on Oct 22, to describe what information would be needed to consider this request. We have not heard back from them, but we sent them a reminder on Thursday. They are aware of what is needed. I'm happy to hop on the phone to discuss this further, if helpful.

Best,

Jessica

From: Menetski, Joseph (FNIH) [T] [REDACTED] b6 >
Sent: Monday, November 16, 2020 2:18 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6
Cc: Tucker, Jessica (NIH/OD) [E] <[REDACTED] b6 : Culp, Michelle (NIH/OD) [E]
<[REDACTED] b6
Subject: RE: Text from Baric chat

Thank you. I am guessing that this will come up in the context of COVID, so it would be good to have all the information and expertise in the room.

Thank you,
Joe

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Sent: Monday, November 16, 2020 2:16 PM
To: Menetski, Joseph (FNIH) [T] <[REDACTED] b6
Cc: Tucker, Jessica (NIH/OD) [E] [REDACTED] b6 ; Culp, Michelle (NIH/OD) [E]
<[REDACTED] b6
Subject: FW: Text from Baric chat

Hi Joe,

I think this is about the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. I've copied my supervisor, Jessica Tucker, who leads the implementation of that policy. There is already some action on this front—Jessica is better suited to describe. Ellen

From: Menetski, Joseph (FNIH) [T] b6
Sent: Monday, November 16, 2020 1:59 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 y>
Subject: FW: Text from Baric chat

Ellen,

As a follow up from a previous discussion from the preclinical working group meeting, we got this text that Ralph received about generating a mutation in the SARS CoV2 virus genome. Her got this from his RIBC.

I am not sure what policy document they are referring to, but I thought that you might? Call me if I am making no sense to you.

Best regards,
Joe

From: Menetski, Joseph (FNIH) [T]
Sent: Monday, November 16, 2020 1:55 PM
To: Young, John <j b6 >; Anderson, James (NIH/OD) [E]
b6 >
Cc: Connelly, Sarah < b6 >; Harrison Hawk b6)
b6 >
Subject: Text from Baric chat

. copy and pasted the text from the chat your us to review and follow up on.

Joe

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/6/2020 2:45:44 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below

Start: 11/6/2020 8:30:00 PM
End: 11/6/2020 9:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/12/2020 7:14:51 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Culp, Michelle (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: Declined: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 11/13/2020 6:00:00 PM
End: 11/13/2020 6:30:00 PM
Show Time As: Busy

Sorry but I have a conflicting meeting tomorrow.

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/6/2020 2:15:33 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Tentative: FNIH + Deloitte ACTIV Touchbase
Location: see webex below

Start: 11/6/2020 10:00:00 PM
End: 11/6/2020 10:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/9/2020 8:03:10 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Accepted: ACTIV Vaccines Working Group meeting
Location: <https://fnih.zoom>. b6
Start: 12/14/2020 5:00:00 PM
End: 12/14/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, Elen (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/9/2020 2:57:10 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below

Start: 12/11/2020 5:00:00 PM
End: 12/11/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, Elen (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/9/2020 2:56:55 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]
Subject: Declined: ACTIV Preclinical full working group
Location: <https://fnih.zoom>. b6
Start: 12/9/2020 3:00:00 PM
End: 12/9/2020 4:00:00 PM
Show Time As: Busy

Sorry but something urgent came up. I'll be on the noon call in case there's anything you want me to know

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/3/2020 2:36:17 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]
Subject: RE: FYI: Agenda for meeting 9th November 2020 11am ET

No, except that FC periodically talks to the Hever group about AMP. David Wholley will know the latest on the AMP gene therapy initiative, and the Tom Hudson initiative refers to ACTIV, and again David would probably have the latest.

From: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, November 3, 2020 8:35 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: FYI: Agenda for meeting 9th November 2020 11am ET

Ellen,

Do you know anything about this? See below.

Thanks,

Jessica

From: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, November 3, 2020 8:30 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: FYI: Agenda for meeting 9th November 2020 11am ET

Hopefully David will help, but just in case, looping in JT because she was peripherally involved in early discussions of this.

From: "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Tue, Nov 3, 2020, 8:13 AM
To: "Wolinetz, Carrie (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: FYI: Agenda for meeting 9th November 2020 11am ET

Hi Carrie

FYI. I'm not sure if I will get pulled into helping with the item below – not too familiar with AMP Gene Therapy but thought I would flag. Maybe David will help here?

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, November 3, 2020 7:49 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: McManus, Ayanna (NIH/OD) [E] <[REDACTED]> **b6** Wood, Gretchen (NIH/OD) [E] <[REDACTED]> **b6**
Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: Agenda for meeting 9th November 2020 11am ET

Hi David,

See attached agenda. I haven't tracked this latest Hever meeting plan very carefully, but I see that I'm now supposed to co-lead a discussion with [REDACTED] b5 on AMP Gene Therapy. Where does that stand?

I'll also need to be prepared to discuss the other topics – what's happened with the Tom Hudson initiative?

Ayanna, this is going to wreck the schedule for Monday November 9.

Francis

From: Jill Payne <[REDACTED] b6>
Sent: Tuesday, November 3, 2020 7:00 AM
To: Jill Payne <[REDACTED] b6>
Subject: Agenda for meeting 9th November 2020 11am ET

For those of you attending, please find attached the agenda for the meeting on Monday, otherwise for interest.

Could presenters please send their slides to Morten Sogaard [REDACTED] b6, by close of business on Friday 6th November for collation into the slide set.

Look forward to seeing you all on Monday!

Kind regards

Jill Payne
On behalf of Hever

Email: [REDACTED] b6
Cell: [REDACTED] b6

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/25/2020 6:32:50 PM
To: Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]
Subject: Re: Lilly product Q

Let me work on a Q and send to you.

Sent from my iPhone

On Oct 25, 2020, at 1:08 PM, Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> wrote:

Ellen,
Yes I know Barney well. But honestly I'm not sure what to ask him — of Lilly used the ACE2 mice and wonder whether this needs to go to the manufacturers?
Sorry but just thinking about being efficient.
Please advise.
Thanks,
Mary

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From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Saturday, October 24, 2020 10:33:16 PM
To: Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: Re: Lilly product Q

Thanks. Do you know him? If you do, could you ask?

Sent from my iPhone

On Oct 23, 2020, at 8:44 PM, Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> wrote:

Barney might be a good place to start.
And I can continue to try to find out more info.
Mary

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From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, October 23, 2020 4:10:36 PM
To: Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: Lilly product Q

Hi Mary,

I have looked at the 2 versions of the IB from Stacey about the Lilly product Bamlanivimab/LY3819253 (LY COV555), but I can't quite put the pieces together and am hoping that you can help.

Where the New York Times article states that Lilly relied on use of HEK cells, they cite the Hassan et al paper. (I think the researchers transduced HEK293 cells with an adenoviral vector expressing the human ACE2 for the purposes of creating an mouse model to use as an alternative to the in-short-supply transgenic mice expressing human ACE2—see Figure 1C.)

The Lilly IB doesn't specifically describe any use of 293 cells, either for assays or for manufacture. The Lilly IB references testing in convalescent plasma from mice, but there is no further detail there that I can find, so I don't know if they used mice that were made as described in the Hassan et al paper.

I am wondering if Barney Graham or John Mascola would know more, as they are authors on a preprint <https://pubmed.ncbi.nlm.nih.gov/33024963/> describing LY-COV555 (but no 293 cell usage mentioned in the main text).

Do you have thoughts or info?

Thanks,
Ellen

From: Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>
Sent: Wednesday, October 21, 2020 2:55 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> Eakin, Ann (NIH/NIAID) [E] <[REDACTED]> Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>
Read, Sarah (NIH/NIAID) [E] <[REDACTED]>
Cc: Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

That works.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, October 21, 2020 1:56 PM
To: Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> Eakin, Ann (NIH/NIAID) [E] <[REDACTED]>; Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>
Read, Sarah (NIH/NIAID) [E] <[REDACTED]>
Cc: Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks, Mary. Sarah suggested that you would be a good central NIAID contact for me on data about Lilly antibodies, so I'll follow up with you separately on those. I'll talk later today with Stacey about information that FNIH may have about the other products lined up for ACTIV-2 and 3.

Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

<image001.png>

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/21/2020 2:43:15 PM
To: Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks

From: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Sent: Wednesday, October 21, 2020 10:42 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Re FNIH, I recommend reaching out directly to Stacey and asking for IBs or other materials that would include data on how the antibodies are produced (they may be stored in a Basecamp community that is used by the Agent Selection Committee. I'm not part of that committee so am just guessing).

Re Lilly, I would start with Mary Marovich. There might be others at the Vaccine Research Center who are more closely involved but Mary would know.

Sarah

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, October 21, 2020 10:36 AM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Sarah,

I think I'm not going to get much help from FNIH, but I will ask them for access to key systems. Can you suggest what I should ask them to give me access to? I've already asked NCATS to give me access to the REDCap survey results. Do you know if the IBs are in REDCap, or should I ask FNIH for them? Are there any other databases or documents that FNIH would have that I should request?

Also, I will pursue further details on the LY-CoV555 with NIAID. Who is the best NIAID contact for me to work with?

Thanks,
Ellen

From: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Sent: Tuesday, October 20, 2020 1:31 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Ellen, to be honest I think Stacey (with support from Deloitte staff) is actually the best person to coordinate this. These questions are related to ACTIV2 and 3, and all these antibodies are coming in through ACTIV not NIAID. LY-CoV555 is the only antibody for which NIAID played a role in discovery. ACTIV has access to the information submitted by the companies (B's etc) and also has the company contacts for asking for more information. NIAID would have to dig for all this information...or ask Stacey for it.

I'm happy to discuss if you have concerns...feel free to call my cell [REDACTED] b6 I'm free now until 3.

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Sent: Tuesday, October 20, 2020 12:56 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED] b6>
Subject: FW: urgent for FC--can reply by 3:25 with any info?

Hi Sarah—thanks again for your quick help yesterday. Do you think the NIAID group can put this information together? I'm not sure who everyone is, and don't want to tell people what to do. I'm happy to play a role here, but am just not sure if that would be useful or not. I copied Melinda because she is also good at coordinating responses and I could go to her with this request instead, if you want. I'm not sure it's fair to ask Stacey to do anything, although she may have good points of contacts at companies.
So appreciate any guidance you have.
Thanks again,
Ellen

From: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED] b6>
Sent: Monday, October 19, 2020 5:53 PM
To: Gadbois, Ellen (NIH/OD) [E] b6; Adam, Stacey (FNIH) [T] b6; Marovich, Mary (NIH/NIAID) [E] b6; Read, Sarah (NIH/NIAID) [E] b6; Tressler, Randall (NIH/NIAID) [E] b6; Eakin, Ann (NIH/NIAID) [E] b6
Cc: Haskins, Melinda (NIH/NIAID) [E] <[REDACTED] b6>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

I agree with Ellen. (And thanks, everyone, for jumping in on this!) Cheers, Carrie

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Sent: Monday, October 19, 2020 4:49 PM
To: Adam, Stacey (FNIH) [T] b6; Marovich, Mary (NIH/NIAID) [E] b6; Read, Sarah (NIH/NIAID) [E] b6; Tressler, Randall (NIH/NIAID) [E] b6; Eakin, Ann (NIH/NIAID) [E] b6
Cc: Haskins, Melinda (NIH/NIAID) [E] b6; Wolinetz, Carrie (NIH/OD) [E] b6
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b4

[REDACTED] b4 For the others, where NIH is not directly involved in R or D, ask the company whether human fetal cells or tissues were used in product research or development and see what they say. (The companies will be getting this question too, so they should get an answer ready...)
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Cc: Haskins, Melinda (NIH/NIAID) [E] b6; Wolinetz, Carrie (NIH/OD) [E] b6
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Hi Ellen,

Just my humble opinion, but #1 is likely easy enough with the IBs, but #2 and #3 could be hard given the number of tests and all the independent testing contracted out. They might take some time unless we are okay with the company just giving us a yes or no answer and trusting them. Others may feel differently.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 Mobile: b6

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Cc: Haskins, Melinda (NIH/NIAID) [E] b6 Adam, Stacey (FNIH) [T] < b6 Wolinetz,
Carrie (NIH/OD) [E] b6 >
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thank you everyone! Sorry about the rush. It seems likely that NIH is going to get more questions along these lines, so it would be great if you could keep digging, but at a more reasonable pace. I think we should know 1) whether the products were made in fetal cell lines, 2) whether there were assays done using fetal lines, 3) whether there was use of fetal tissue or cells in making a mouse as part of the research, and for any of those items, the source/reference of the info. Would it make sense to start a table? I am happy to help although you may have better ways of compiling the information on a NIAID system. Just let me know. Ellen

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To: Marovich, Mary (NIH/NIAID) [E] b6 Adam, Stacey (FNIH) [T] b6 Read, Sarah
(NIH/NIAID) [E] b6 >; Gadbois, Ellen (NIH/OD) [E] b6 >; Tressler, Randall
(NIH/NIAID) [E] b6 >; Eakin, Ann (NIH/NIAID) [E] b6
Cc: Haskins, Melinda (NIH/NIAID) [E] < b6
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Sent: Monday, October 19, 2020 4:10 PM
To: Adam, Stacey (FNIH) [T] b6 >; Read, Sarah (NIH/NIAID) [E] < b6 >; Gadbois, Ellen
(NIH/OD) [E] b6 >; Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann
(NIH/NIAID) [E] < b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 > Haskins, Melinda (NIH/NIAID) [E]
b6
Subject: Re: urgent for FC--can reply by 3:25 with any info?

Thx Stacey - and do we know about the 2nd mAb in the cocktail?

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From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Monday, October 19, 2020 4:09:23 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]>; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>;
Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>; Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>;
Eakin, Ann (NIH/NIAID) [E] <[REDACTED]>
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi All,

Just responded to Ellen LY-CoV555 is manufactured in CHO (Chinese Hamster Ovary) cell line.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] Mobile: [REDACTED]

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Sent: Monday, October 19, 2020 3:56 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>;
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Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>;
Adam, Stacey (FNIH) [T] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Copying Stacey as well. Stacey, who do you think would be the best contact at Lilly for this question (highlighted below)? Carl?

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Monday, October 19, 2020 3:52 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]>; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>;
Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]>
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

FYI the NY Times reported:

https://www.nytimes.com/2020/10/08/health/trump-covid-fetal-tissue.html?auth=login_email&login=email
"Regeneron tested the antibodies against virus like particles created using 293T human cells. The viral particles serve as a proxy for the live coronavirus; testing otherwise would require a lab with extremely high biosafety levels. (Eli Lilly, which also is manufacturing monoclonal antibodies, is using the same method.)"

See Figure 1 in methods paper cited in the Times article:
<https://www.sciencedirect.com/science/article/pii/S009286742030742X>

A SARS-CoV-2 Infection Model in Mice Demonstrates Protection by Neutralizing Antibodies

Figure 1. SARS-CoV-2 Infection in Conventional Laboratory Strains of Mice and Expression of hACE2 after AdV Transduction

(C) HEK293 cells were transduced with AdV-hACE2-GFP. Flow cytometric analysis of hACE2 and GFP expression was analyzed at 4 and 10 h after AdV transduction. One of two experiments is shown.

Can Lilly confirm usage of HEK293 and was there any other human fetal cell use for that mAb, and do we know anything about the other mAbs lined up for ACTIV-2 or 3? (We already know about Regeneron.)

Thank you!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, October 19, 2020 3:43 PM
To: Read, Sarah (NIH/NIAID) [E] b6 >; Marovich, Mary (NIH/NIAID) [E] b6 >;
Tressler, Randall (NIH/NIAID) [E] b6 Eakin, Ann (NIH/NIAID) [E] b6
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 ; Haskins, Melinda (NIH/NIAID) [E]
b6 >
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks, all. Just to list them together: commonly used immortalized cell lines original from HFT and used for various purposes are PERC6, WI-38, MRC-5, and HEK293.

From: Read, Sarah (NIH/NIAID) [E] < b6
Sent: Monday, October 19, 2020 3:42 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 >; Marovich, Mary (NIH/NIAID) [E] b6
Tressler, Randall (NIH/NIAID) [E] < b6 >; Eakin, Ann (NIH/NIAID) [E] b6
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 Haskins, Melinda (NIH/NIAID) [E]
b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Adding in Ann Eakin as well. Ann, see highlighted queries below.

From: Read, Sarah (NIH/NIAID) [E]
Sent: Monday, October 19, 2020 3:40 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 Marovich, Mary (NIH/NIAID) [E] b6 >;
Tressler, Randall (NIH/NIAID) [E] b6
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 Haskins, Melinda (NIH/NIAID) [E]
< b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?
Importance: High

Ellen, I apologize I just got off a call and am just seeing your note now. I don't know the answer to your query. I'm copying Mary Marovich and Randy Tressler who might know better than I.

Mary and Randy if you have knowledge of the cell line(s) used by Lilly please respond to Ellen.

Thanks

From: Gadbois, Ellen (NIH/OD) [E] < b6 >
Sent: Monday, October 19, 2020 3:18 PM
To: Read, Sarah (NIH/NIAID) [E] < b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 >; Haskins, Melinda (NIH/NIAID) [E]
b6 >
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Just FYI WI 38 and MRC 5 are other old cell lines from human fetal tissue used in vaccine production and for other purposes—they are also immortalized.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, October 19, 2020 3:17 PM
To: Read, Sarah (NIH/NIAID) [E] b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 >; Haskins, Melinda (NIH/NIAID) [E]
< b6 >
Subject: urgent for FC--can reply by 3:25 with any info?

Hi Sarah,
Sorry for the urgent request, but something is happening at 3:30 today and Dr. Collins would appreciate receiving any info we have on the use of human fetal cell lines (or human fetal tissue) in the development or production of monoclonal antibodies vs. COVID-19. I already sent what I have on the use of HEK293T cells by Regeneron. Do you know if Lilly is using HEK293 or any of the other old fetal cells lines for their monoclonal? Or do you know about the other companies with products being considered for ACTIV-2 or ACTIV-3?
Thanks,
Ellen Gadbois

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280



National Institutes of Health
Turning Discovery Into Health

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/28/2020 3:01:24 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Tentative: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 11/4/2020 5:00:00 PM
End: 11/4/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/28/2020 3:01:06 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 11/6/2020 6:00:00 PM
End: 11/6/2020 6:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
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Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 11/13/2020 6:00:00 PM
End: 11/13/2020 6:30:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/20/2020 5:40:37 PM
To: Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks. I'm going to check back in with Carrie W. on this and then will get back to you.

From: Read, Sarah (NIH/NIAID) [E] <[REDACTED]>
Sent: Tuesday, October 20, 2020 1:31 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Ellen, to be honest I think Stacey (with support from Deloitte staff) is actually the best person to coordinate this. These questions are related to ACTIV2 and 3, and all these antibodies are coming in through ACTIV not NIAID. LY-CoV555 is the only antibody for which NIAID played a role in discovery. ACTIV has access to the information submitted by the companies (B's etc) and also has the company contacts for asking for more information. NIAID would have to dig for all this information...or ask Stacey for it.

I'm happy to discuss if you have concerns...feel free to call my cell [REDACTED] I'm free now until 3.

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So appreciate any guidance you have.
Thanks again,
Ellen

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I agree with Ellen. (And thanks, everyone, for jumping in on this!) Cheers, Carrie

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(NIH/NIAID) [E] < b6
Cc: Haskins, Mel nda (NIH/NIAID) [E] b6 . Wolinetz, Carrie (NIH/OD) [E]
b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

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Thx Stacey - and do we know about the 2nd mAb in the cocktail?

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Hi All,

Just responded to Ellen LY-CoV555 is manufactured in CHO (Chinese Hamster Ovary) cell line.

Thanks,
Stacey

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Direct: b6 , Mobile: b6

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Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6 Haskins, Melinda (NIH/NIAID) [E]
b6 Adam, Stacey (FNIH) [T] b6

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Copying Stacey as well. Stacey, who do you think would be the best contact at Lilly for this question (highlighted below)? Carl?

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Cc: Wolinetz, Carrie (NIH/OD) [E] b6 Haskins, Melinda (NIH/NIAID) [E]
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FYI the NY Times reported:

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"Regeneron tested the antibodies against virus-like particles created using 293T human cells. The viral particles serve as a proxy for the live coronavirus; testing otherwise would require a lab with extremely high biosafety levels. (Eli Lilly, which also is manufacturing monoclonal antibodies, is using the same method.)"

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Figure 1. SARS-CoV-2 Infection in Conventional Laboratory Strains of Mice and Expression of hACE2 after AdV Transduction

(C) HEK293 cells were transduced with AdV-hACE2-GFP. Flow cytometric analysis of hACE2 and GFP expression was analyzed at 4 and 10 h after AdV transduction. One of two experiments is shown.

Can Lilly confirm usage of HEK293 and was there any other human fetal cell use for that mAb, and do we know anything about the other mAbs lined up for ACTIV-2 or 3? (We already know about Regeneron.)

Thank you!

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b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks, all. Just to list them together: commonly used immortalized cell lines original from HFT and used for various purposes are PERC6, WI-38, MRC-5, and HEK293.

From: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Sent: Monday, October 19, 2020 3:42 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> **b6**
Tressler, Randall (NIH/NIAID) [E] <[REDACTED]> **b6**; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> **b6**; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Adding in Ann Eakin as well. Ann, see highlighted queries below.

From: Read, Sarah (NIH/NIAID) [E] <[REDACTED]>
Sent: Monday, October 19, 2020 3:40 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> **b6**
Tressler, Randall (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> **b6**; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?
Importance: High

Ellen, I apologize I just got off a call and am just seeing your note now. I don't know the answer to your query. I'm copying Mary Marovich and Randy Tressler who might know better than I.

Mary and Randy if you have knowledge of the cell line(s) used by Lilly please respond to Ellen.

Thanks

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** >
Sent: Monday, October 19, 2020 3:18 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> **b6**; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Just FYI WI-38 and MRC-5 are other old cell lines from human fetal tissue used in vaccine production and for other purposes—they are also immortalized.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Monday, October 19, 2020 3:17 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> **b6**; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: urgent for FC--can reply by 3:25 with any info?

Hi Sarah,

Sorry for the urgent request, but something is happening at 3:30 today and Dr. Collins would appreciate receiving any info we have on the use of human fetal cell lines (or human fetal tissue) in the development or production of monoclonal antibodies vs. COVID-19. I already sent what I have on the use of HEK293T cells by Regeneron. Do you know if Lilly is using HEK293 or any of the other old fetal cells lines for their monoclonal? Or do you know about the other companies with products being considered for ACTIV-2 or ACTIV-3?

Thanks,
Ellen Gadbois

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218

voice: **b6**

fax: **b6**



National Institutes of Health
Turning Discovery Into Health

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/25/2020 5:08:05 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV EC & Working Group Co-Chair Meeting
Location: <https://fnih.zoom.us/j/> b6
Start: 11/4/2020 3:00:00 PM
End: 11/4/2020 4:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/25/2020 4:45:27 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below

Start: 9/30/2020 5:00:00 PM
End: 9/30/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/25/2020 4:45:18 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 10/2/2020 7:00:00 PM
End: 10/2/2020 7:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/16/2020 4:59:19 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 10/21/2020 8:00:00 PM
End: 10/21/2020 8:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/16/2020 4:59:07 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 10/23/2020 5:00:00 PM
End: 10/23/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/16/2020 4:59:00 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH+ Deloitte ACTIV Touchbase
Location: see webex below
Start: 10/28/2020 5:30:00 PM
End: 10/28/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/5/2020 2:25:07 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Accepted: ACTIV Preclinical full working group
Location: <https://fnih.zoom.us/> b6
Start: 10/8/2020 1:00:00 PM
End: 10/8/2020 2:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/13/2020 12:37:11 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV Therapeutics-Clinical Working Group Meeting
Location: <https://fnih.zoom.us/> b6
Start: 10/15/2020 5:00:00 PM
End: 10/15/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/24/2020 7:48:52 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Declined: ACTIV Preclinical full working group
Location: <https://fnih.zoom.us/j/> b6
Start: 8/26/2020 2:00:00 PM
End: 8/26/2020 3:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/2/2020 6:09:42 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 9/9/2020 7:30:00 PM
End: 9/9/2020 8:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/10/2020 7:51:51 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 9/11/2020 8:00:00 PM
End: 9/11/2020 8:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/18/2020 5:21:51 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Declined: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 9/25/2020 3:00:00 PM
End: 9/25/2020 3:30:00 PM
Show Time As. Busy

Have conflict with another meeting

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/2/2020 5:37:43 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 10/9/2020 5:30:00 PM
End: 10/9/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 10/2/2020 5:37:33 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 10/14/2020 5:30:00 PM
End: 10/14/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/29/2020 4:01:51 PM
To: Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]
Subject: could I pass along your email to a AAAS fellow?

Hi Steve,

I hope that all is well with you. I'm writing because I recently spoke to a new NIH AAAS fellow, Ryan Richardson. Ryan is placed at NINDS and so will probably be there for 2 years. He was particularly interested in hearing about how public-private partnerships work. I talked to him about AMP and a little about ACTIV, and he was wondering if someone at FNIH would be willing to talk to him about how FNIH operates. Would you be willing, and could I give him your email address?

Thanks,
Ellen

From: Richardson, Ryan (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, September 17, 2020 2:45 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Cheng, Irene (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Introduction - Ryan Richardson (STPF - BRAIN Initiative) and Ellen Gadbois (OSP - Emerging Biotech Team)

Hi Ellen,

As a new AAAS STPF Fellow working with John Ngai and his team at the Office of the BRAIN Director at NINDS, I wanted to take a moment to introduce myself to you briefly. Before coming to the NIH, I was a postdoc in a developmental neuroscience lab for 3 years at the University of Maryland Baltimore after having earned my Ph.D. studying synthetic biology at Harvard University. Beyond the bench, I have been, and continue to be interested in both business development and science education/outreach as ways to greater impact diverse communities.

One of my first challenges as a member of the team at BRAIN is simply to understand more about the structure and scope of BRAIN, and how this fits into the larger vision of both NINDS and NIH as a whole. Towards that goal, in speaking with Irene about my background, interests, and some of the activities I will get involved with through BRAIN, she recommended that I reach out to you to learn more about you and the multiple roles you play within OSP. Would it be possible for us to schedule 30 minutes to chat sometime in the coming weeks?

Thank you for your attention in reading this, and I look forward to connecting with you soon.

All the best,
Ryan

--

Ryan Richardson, Ph.D.
AAAS Science & Technology Policy Fellow
Health Scientist
Office of the BRAIN Director, NINDS
National Institutes of Health
E: [REDACTED] **b6**
T: [REDACTED] **b6**

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/18/2020 5:21:23 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 9/23/2020 9:00:00 PM
End: 9/23/2020 9:30:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/1/2020 7:49:27 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: finding ACTIV trials in ClinicalTrials.gov search

Thanks for boiling it down so nicely.

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, September 1, 2020 2:47 PM
To: Brennan, Patti (NIH/NLM) [E] <[REDACTED]> **b6** Williams, Rebecca (NIH/NLM/NCBI) [E] <[REDACTED]> **b6** Dobbins, Heather (NIH/NLM/NCBI) [E] <[REDACTED]> **b6**
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** Johnson, Lenora (NIH/NHLBI) [E] <[REDACTED]> **b6** Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: finding ACTIV trials in ClinicalTrials.gov search

Dear Patti, Becky and Heather,

The ACTIV study teams would like to learn how to make the ACTIV trials be more easily found in a ClinicalTrials.gov search.

They would like to know if there is a way to prioritize the ACTIV trials in a ClinicalTrials.gov search so that ACTIV studies come up higher (or at the top) in search result.

- What terms can be added to the registration record to make ACTIV trials higher up on the search result?
- Is it possible to have the ACTIV trials linked in the peach colored box or near the top of the list of the COVID-19 search result? (see paste below.)
- Who on your team can the speak to about this?

Thank you for your help!

All the best,
Michelle

Home > Search Results

Modify Search

Start Over

79 Studies found for COVID-19; NIH, U.S. Fed

Also searched for COVID and SARS-CoV-2 [See Search Details](#)Applied Filters: ☒ Funding: NIH ☒ Funding: U.S. Federal

Your search included COVID-19

Learn more about clinical studies related to COVID-19

- [ClinicalTrials.gov](#) Federally funded clinical studies related to COVID-19
- [WHO Trial Registry Network](#) COVID-19 studies from the ICTRP data base
- [NIH COVID-19 Treatment Guidelines](#)
- [ClinicalTrials.gov](#) [View all listed COVID-19 Studies](#)

List

By Topic

On Map

Search Details

Hide Filters

Filters

Clear

Status

Recruitment

Not yet recruiting

Recruiting

Enrolling by invitation

Showing 1 to 79 studies 10 studies per page

Show Map > X-RAYS

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1			Phase 1/2a Study of the Efficacy and Safety of the SARS-CoV-2 Vaccine (mRNA-1273) in Healthy Adults	<ul style="list-style-type: none">SARS-CoV-2COVID-19	<ul style="list-style-type: none">Drug: HydroxychloroquineDrug: AzithromycinDrug: Placebo	<ul style="list-style-type: none">San Francisco, CASan Francisco, CaliforniaUnited States
2			Phase 1/2a Study of the Efficacy and Safety of the COVID-19 Vaccine (mRNA-1273) in Healthy Adults	<ul style="list-style-type: none">COVID-19		<ul style="list-style-type: none">NIH Clinical Research Unit (CRU)

From: Godin, Jacquelyn (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CC88D464EFC34115904F29A975AEEB85-GODINJA]
Sent: 6/16/2020 8:43:31 PM
To: Klock, Kevin (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6a4795309e54d3d887b0051aa88183b-klockka]
CC: Lankford, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
Subject: RE: ACTIV: Revised Antitrust Policy
Attachments: ACTIV Antitrust Guidelines 6-16-20 for external review.docx; Antitrust - Redline.docx; RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Thanks, Kevin I've copied Ann Martin here. Ann is the lead for ACTIV in our office. Please work with her and David directly.

Hope all is well,
-Jackie

Jacquelyn A. Godin, JD, MPH
Senior Attorney
NIH Branch, Public Health Division
HHS Office of the General Counsel
b6 (direct)
b6

This message is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, or protected. It should not be disseminated, distributed or copied to persons not authorized to receive such information.

From: Klock, Kevin (FNIH) [T] <b6>
Sent: Tuesday, June 16, 2020 4:16 PM
To: Lankford, David (NIH/OD) [E] <b6> Godin, Jacquelyn (NIH/OD) [E]
<b6>
Subject: ACTIV: Revised Antitrust Policy

Hi David and Jackie –

I hope you are doing well. I am aware that Ellen Gadbois sent to you or someone on your team the draft ACTIV Antitrust Policy and Guidelines (her email attached).

In the meantime, b4 sent through some changes that we thought were acceptable. There are a couple clean-up edits too.

So attached are clean and redlined versions of the Policy and Guidelines for your review that supersede what was sent a few days ago. Do you have a sense when NIH will complete its review?

Many thanks,
Kevin

Kevin A. Klock
Vice President of Operations and General Counsel
Foundation for the National Institutes of Health

GADB0000000565

b6

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/11/2020 7:36:46 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Klock, Kevin (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6a4795309e54d3d887b0051aa88183b-klockka]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Got it. I'm sending it to our OGC now—I already gave them a heads up that this would be coming

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, June 11, 2020 3:33 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Klock, Kevin (FNIH) [T] <[REDACTED]> **b6**
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen —

b5

Thanks for your help.

David

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/18/2020 4:24:44 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Call #8
Location: <https://fnih.zoom.us/> b6
Start: 9/23/2020 1:00:00 PM
End: 9/23/2020 2:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/18/2020 4:24:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV EC & Working Group Co-Chair Meeting
Location: <https://fnih.zoom>. b6
Start: 10/7/2020 2:00:00 PM
End: 10/7/2020 3:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/18/2020 4:24:26 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Call #9
Location: <https://fnih.zoom>. b6
Start: 10/21/2020 4:00:00 PM
End: 10/21/2020 5:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/18/2020 4:24:22 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Pre-call
Location: see webex below
Start: 10/16/2020 5:30:00 PM
End: 10/16/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/18/2020 4:22:53 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: Pre-Call for ACTIV Leadership Call
Location: see webex below
Start: 9/21/2020 8:00:00 PM
End: 9/21/2020 8:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/4/2020 3:35:26 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Declined: ACTIV Preclinical full working group
Location: <https://fnih.zoom.us/> b6
Start: 8/12/2020 2:00:00 PM
End: 8/12/2020 3:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/18/2020 4:22:50 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV EC Pre-call
Location: see webex below
Start: 10/2/2020 5:00:00 PM
End: 10/2/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/18/2020 2:47:18 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]
Subject: Accepted: ACTIV EC & Working Group Co-Chair Meeting
Location: <https://fnih.zoom.us/j/92011111111>
Start: 9/9/2020 1:00:00 PM
End: 9/9/2020 2:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/16/2020 1:02:24 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Declined: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 9/16/2020 1:30:00 PM
End: 9/16/2020 2:00:00 PM
Show Time As. Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/18/2020 2:47:06 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV EC Pre-call
Location: see webex
Start: 9/8/2020 5:00:00 PM
End: 9/8/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/1/2020 1:25:17 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV Therapeutics-Clinical Working Group Meeting
Location: <https://fnih.zoom.us/j/9181111111> b6
Start: 9/10/2020 5:00:00 PM
End: 9/10/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/27/2020 8:42:30 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: Microsoft Teams Meeting
Start: 7/29/2020 4:30:00 PM
End: 7/29/2020 5:00:00 PM
Show Time As: Busy

From: Gadbois, Elen (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 9/1/2020 1:25:10 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV EC & Working Group Co-Chair Meeting
Location: <https://fnih.zoom.us/j/> b6
Start: 9/9/2020 6:30:00 PM
End: 9/9/2020 7:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/24/2020 8:07:56 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: Microsoft Teams Meeting
Start: 7/28/2020 4:00:00 PM
End: 7/28/2020 4:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/24/2020 8:07:44 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Tentative: FNIH + Deloitte ACTIV Touchbase
Location: Microsoft Teams Meeting
Start: 7/31/2020 9:00:00 PM
End: 7/31/2020 9:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/15/2020 5:10:20 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: Daily ACTIV Touchbase (FNIH + Deloitte)
Location: see webex below
Start: 7/16/2020 8:00:00 PM
End: 7/16/2020 8:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/28/2020 7:25:06 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 9/4/2020 5:00:00 PM
End: 9/4/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/21/2020 7:00:29 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Team Pre-call
Location: see webex below
Start: 8/24/2020 4:00:00 PM
End: 8/24/2020 4:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/28/2020 7:25:01 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 9/2/2020 1:00:00 PM
End: 9/2/2020 1:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/14/2020 6:38:36 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Tentative: ACTIV Leadership Team Call #7
Location: <https://fnih.zoom.us/j/> b6
Start: 8/26/2020 7:00:00 PM
End: 8/26/2020 8:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDECS66C26C2A-GADBOISEL]
Sent: 9/3/2020 1:50:42 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Young, Cari (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7765319e02c347ed8466c56e5ae61be5-youngce]
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

I'll do that now and cc you.

From: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, September 3, 2020 9:49 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**; Young, Cari (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

I am crashing on other stuff- will try to figure this out later, but OK with me if it makes sense for you to ask Jessica C.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** >
Sent: Thursday, September 3, 2020 9:43 AM
To: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**; Young, Cari (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

I'm confused. I think Tyrone needs to clarify who is supposed to write the narratives. We have opposing directions:

1. Sections of the CJ narrative have already been assigned to various groups. Lauren, Michelle, Ashley and I have the ACTIV section and created the outline. Yesterday Jessica Creery wrote asking that we finish the ACTIV narrative by Oct 23 (attached).
2. But at the bottom this current email chain, Erica Landis (IMOD) writes: "IMOD will be taking the first pass at writing the Narrative section, the source material you contribute will be used to inform the writing process. For topics to submit source material on, please refer to the blue text in the CJ outline which indicates which OD Offices have played a role in each topic."

So I don't know who is doing the writing. But if it's IMOD, then we had better identify all of the sources they might use. FYI I'm not sure how IMOD will write up AMP, since there's no longer a good source since the BRAIN topic got archived. There is stuff on the NIH website, but it's (intentionally) pretty general.

Jessica, do you want to take this up with Tyrone? Alternatively I can write to Jessica C since she just asked the ACTIV team to write that narrative.

From: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, September 3, 2020 9:11 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6**; Young, Cari (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Thanks. If the topic is not relevant to us, we just won't submit anything. I think Tyrone was just guessing what might be OSP-relevant.

From: "Gadbois, Ellen (NIH/OD) [E]" b6
Date: Thu, Sep 3, 2020, 8:49 AM
To: "Tucker, Jessica (NIH/OD) [E]" < b6
CC: "Brodd, Lauren (NIH/OD) [E]" b6 >, "Young, Cari (NIH/OD) [E]" < b6
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Got it. I will respond on AMP.

I am not sure who in OSP is dealing with the All of Us COVID testing, but that's not an ACTIV function. I don't know what All of Us is doing there.

I'm also not sure who is handling the BRAIN Initiative part, but presumably they will know to include the BNS report to the ACD as source material.

From: Tucker, Jessica (NIH/OD) [E] b6
Sent: Thursday, September 3, 2020 7:12 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 ; Young, Cari (NIH/OD) [E] b6
Cc: Brodd, Lauren (NIH/OD) [E] b6
Subject: FW: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Ellen and Cari (and ccing Lauren for awareness),

Looping you in re: AMP, COVID, and AI. I have not looked at this yet, but my guess is we would be unlikely to have anything for COVID or AI, but perhaps for AMP. Based on the subject line, I think Tyrone is looking for edits by 12 PM tomorrow.

Thanks,

Jessica

From: Spady, Tyrone (NIH/OD) [E] < b6
Sent: Wednesday, September 2, 2020 7:00 PM
To: Bayha, Ryan (NIH/OD) [E] < b6 Berger, Adam (NIH/OD) [E] b6 >; Diggs, Susan
(NIH/OD) [E] < b6 Fennington, Kelly (NIH/OD) [E] < b6 >; Isaacman-Beck, Jesse
(NIH/OD) [E] b6 >; Jorgenson, Lyric (NIH/OD) [E] < b6 >; Koniges, Ursula
(NIH/OD) [E] b6 >; Paine, Taunton (NIH/OD) [E] b6 >; Rohrbaugh, Mark
(NIH/OD) [E] b6 >; Tucker, Jessica (NIH/OD) [E] < b6 Wolinetz, Carrie (NIH/OD)
[E] b6 >; Gadbois, Ellen (NIH/OD) [E] b6 >
Cc: Creery, Jessica (NIH/OD) [E] b6
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Hi all:

It looks like some of you might not have access to the Teams site. As work-arounds, I'm attaching the full OD CJ outline and please send your additions to me and Jessica Creery. We can upload for you.

Cheers,

T-

From: Spady, Tyrone (NIH/OD) [E] <b6>
Sent: Wednesday, September 2, 2020 5:47 PM
To: Bayha, Ryan (NIH/OD) [E] <b6> gov>, Berger, Adam (NIH/OD) [E] <b6>; Diggs, Susan (NIH/OD) [E] <b6>; Fennington, Kelly (NIH/OD) [E] <b6>; Isaacman-Beck, Jesse (NIH/OD) [E] <b6>; Jorgenson, Lyric (NIH/OD) [E] <b6>; Koniges, Ursula (NIH/OD) [E] <b6>; Paine, Taunton (NIH/OD) [E] <b6>; Rohrbaugh, Mark (NIH/OD) [E] <b6>; Spady, Tyrone (NIH/OD) [E] <b6>; Tucker, Jessica (NIH/OD) [E] <b6>; Wolinetz, Carrie (NIH/OD) [E] <b6>; Gadbois, E len (NIH/OD) [E] <b6>
Cc: Creery, Jessica (NIH/OD) [E] <b6>
Subject: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Hi all:

IMOD has issued a call for source material (reports, websites, formal announcements, etc...) for the OD Congressional Justification narrative (see below). Some of you may have already provided your contributions. If so, please let me know. We've listed the topics where OSP might have source materials to add. Please add any relevant source material on the subjects listed below (Full doc: [OD CJ Outline](#)) to the Teams folder named "[Narrative Source Material](#)" by COB on Friday, September 4th. Let me know if you have any questions.

OSP relevant subjects

1. **BRAIN Initiative updates**
2. **Accelerating Medicines Partnerships**
3. **NIH efforts on Data Science and Artificial Intelligence**
 1. **Data sharing policies**
 2. **Harnessing Data Science for Health Discovery and Innovation in Africa**
 3. **Artificial Intelligence for Biomedical Excellence (AIBLE) program**
 4. **Artificial Intelligence to address chronic disease**
 5. **Collaboration with NASEM on Behavioral Ontologies**
 6. **Updating MeSH terms**
4. **Rigor and Reproducibility**
 1. **ACD Working Group on Enhancing Reproducibility and Rigor in Animal Research**
5. **Program Portraits**
 1. **All of Us COVID-19 Testing, highlighting the Electronic Health Record Data survey to provide researchers with easy to use data on how participants are experiencing COVID-19 while maintaining privacy**
 2. **Strengthening Anti-Harassment Policies at NIH, updates from the ACD Working Group, implementation of new policies, and support for continued growth and development**
 3. **Updating the NIH-wide Strategic Plan, a trans-NIH effort guided by the OD to outline the NIH vision for biomedical research, opportunities for scientific exploration, and address new challenges for the next five years.**

Cheers,
Tyrone

From: Landis, Erica (NIH/OD) [E] <b6>
Sent: Tuesday, September 1, 2020 5:09 PM
To: Culhane, Ned (NIH/OD) [E] <b6> Hentges, Justin (NIH/OD) [E] <b6>
Heath-Mason, Matthew (NIH/OD) [E] <b6>; Le Fauve, Charlene (NIH/OD) [E] <b6>; Kawazoe, Robin (NIH/OD) [E] <b6>; Spady, Tyrone (NIH/OD) [E] <b6>; Creery, Jessica (NIH/OD) [E] <b6>; Noursi, Samia (NIH/OD) [E] <b6>; Morris, Patricia (NIH/NICHD) [E] <b6>; Luetkemeier, Erin (NIH/OD) [E] <b6>

< b6 Klock, Kevin (FNIH) [T] < b6 Edghill Spano, Yvette (NIH/OD) [E]
 < b6 >; Espinoza, Tasha (NIH/OD) [E] < b6 Morris, Kathryn (NIH/OD) [E]
 b6 Myles, Renate (NIH/OD) [E] b6 ; Burklow, John (NIH/OD) [E]
 b6 >; Peterman Cross, Wilma (NIH/OD) [E] < b6 ; Thurn, Anne (NIH/OD) [E]
 b6 Kosub, David (NIH/OD) [E] b6 ; Columbus, Megan (NIH/OD) [E]
 b6 >; Rabin, Elise (NIH/OD) [E] b6 >; Owens, Roland (NIH/OD) [E]
 < b6 Murray, Darryl (NIH/OD) [E] b6 ; Shorback, Janet (NIH/OD) [E]
 < b6 Stevens, Mark (NIH/OD) [E] < b6 Newman, Patricia (NIH/OD) [E]
 b6 Spencer, Elizabeth (NIH/OD) [E] b6 ; Ekweani, Elonna (NIH/OD) [E]
 < b6 >; Vonkollmar, Desiree (NIH/OD) [E] < b Courchesne, Stephanie (NIH/OD)
 [E] < b6 >; Fennington, Kelly (NIH/OD) [E] b6 Spaniol, Erin (NIH/OD) [E]
 b6 ; Baker, Rebecca (NIH/OD) [E] b6

Cc: Mazzucco, Anna (NIH/OD) [E] < b

Subject: Re: Request: Source material for OD CJ Narrative draft

Dear all,

Thank you to those who have already provided source material for the OD Congressional Justification narrative. If you have not had a chance to yet, please add any relevant source material on the subjects listed in the OD CJ Outline to the Teams folder named "Narrative Source Material" by COB on Friday, September 4th.

Please feel free to reach out with any questions you have.

Very best,
 Erica

Erica G. Landis, PhD
 AAAS Science & Technology Policy Fellow
 Immediate Office of the Director
 National Institutes of Health
 A: Building 1, Room 114
 P: b6

From: "Land's, Erica (NIH/OD) [E]" < b6
 Date: Monday, August 24, 2020 at 12:04 PM
 To: "Culhane, Ned (NIH/OD) [E]" < b6 >, "Hentges, Justin (NIH/OD) [E]"
 < b6 >, "Heath-Mason, Matthew (NIH/OD) [E]" b6 >, "Le
 Fauve, Charlene (NIH/OD) [E]" b6 "Kawazoe, Robin (NIH/OD) [E]"
 b6 "Spady, Tyrone (NIH/OD) [E]" < b6 >, "Creery, Jessica (NIH/OD)
 [E]" b6 "Noursi, Samia (NIH/OD) [E]" b6 >, "Morris, Patricia
 (NIH/NICHD) [E]" b6 >, "Luetkemeier, Erin (NIH/OD) [E]" b6
 "Klock, Kevin (FNIH) [T]" b6 Edghill Spano, Yvette (NIH/OD) [E]"
 b6 >, "Espinoza, Tasha (NIH/OD) [E]" b6 >, "Morris, Kathryn
 (NIH/OD) [E]" b6 >, "Myles, Renate (NIH/OD) [E]" b6 >, "Burklow,
 John (NIH/OD) [E]" < b6 >, "Peterman Cross, Wilma (NIH/OD) [E]"
 < b6 >, "Thurn, Anne (NIH/OD) [E]" b6 "Kosub, David (NIH/OD) [E]"
 < b6 >, "Columbus, Megan (NIH/OD) [E]" b6 >, "Rabin, Elise (NIH/OD)
 [E]" b6 >, "Owens, Roland (NIH/OD) [E]" b6 >, "Murray, Darryl (NIH/OD)
 [E]" b6 >, "Shorback, Janet (NIH/OD) [E]" b6 >, "Stevens, Mark

(NIH/OD) [E]" b6 "Newman, Patricia (NIH/OD) [E]" < b6
"Spencer, Elizabeth (NIH/OD) [E]" b6 "Ekweani, Elonna (NIH/OD) [E]"
b6 > "Vonkollmar, Desiree (NIH/OD) [E]" b6 "Courchesne,
Stephanie (NIH/OD) [E]" <st b6 "Fennington, Kelly (NIH/OD) [E]"
< b6 "Spaniol, Erin (NIH/OD) [E]" b6 "Baker, Rebecca (NIH/OD) [E]"
b6 >

Cc: Anna Mazzucco < b6

Subject: Request: Source material for OD CJ Narrative draft

Dear all,

Thank you for all of your help in developing the OD Congressional Justification outline. Please see below a request for our next step.

ASK: Please submit any relevant source material on the subjects listed in the [OD CJ Outline](#) to the Teams folder named "[Narrative Source Material](#)" by **COB on Friday, September 4th**.

Background and Process: We greatly appreciate your help in developing the OD Congressional Justification outline for FY22. As the FY22 CJ Outline moves through the OLPA review process, we would like to begin collecting source material for the CJ Narrative to support the initial drafting process. IMOD will be taking the first pass at writing the Narrative section, the source material you contribute will be used to inform the writing process. For topics to submit source material on, please refer to the blue text in the CJ outline which indicates which OD Offices have played a role in each topic. Source material can include previously written or new reports, press releases, analyses, or any other documents which describe the program or topic. Once the Narrative is drafted, we will distribute it to you for your review before submission to OLPA.

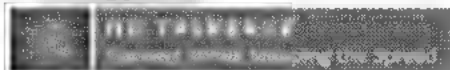
For a reminder on the timeline for the OD CJ, please refer to the [Timeline](#) tab in Teams.

Please let us know if you have any questions or concerns. We appreciate you taking the time to provide feedback. Thank you in advance for your input!

Much appreciation,
Erica

Erica G. Landis, PhD
AAAS Science & Technology Policy Fellow
Immediate Office of the Director
National Institutes of Health
A: Building 1, Room 114

P: b6



From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/7/2020 3:21:58 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 8/14/2020 7:30:00 PM
End: 8/14/2020 8:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/7/2020 3:21:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Declined: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 8/12/2020 3:30:00 PM
End: 8/12/2020 4:00:00 PM
Show Time As: Busy

On annual leave

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/30/2020 3:48:36 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 8/7/2020 5:30:00 PM
End: 8/7/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, Elen (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/7/2020 1:20:50 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Tentative: ACTIV Therapeutics-Clinical Working Group Meeting
Location: <https://fnih.zoom.us/j/>, b6
Start: 6/25/2020 5:00:00 PM
End: 6/25/2020 6:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/6/2020 6:41:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Tentative: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
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End: 8/7/2020 9:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 2/17/2021 8:33:24 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH/Deloitte ACTIV Touchbase
Location: see webex below
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End: 2/19/2021 8:00:00 PM
Show Time As: Busy

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Sent: 7/17/2020 1:34:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 7/24/2020 5:00:00 PM
End: 7/24/2020 5:30:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/10/2020 7:32:05 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: REDCap questions

Actually I forgot—I have to b6 thing about 4:35....is 4:15 OK?

From: Menetski, Joseph (FNIH) [T] < b6 >
Sent: Friday, July 10, 2020 3:29 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 >
Subject: RE: REDCap questions

How about 4:30? I can send an invite.

Joe

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Friday, July 10, 2020 3:25 PM
To: Menetski, Joseph (FNIH) [T] < b6 >
Subject: RE: REDCap questions

Thanks. When is good for you? I have time after the 3:30 catchup call if that works.

From: Menetski, Joseph (FNIH) [T] b6
Sent: Friday, July 10, 2020 3:08 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 > Wholley, David (FNIH) [T] < b6 > Adam, Stacey (FNIH) [T] < b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6 Parker, Ashley (NIH/OD) [E] < b6 >
Subject: RE: REDCap questions

Sorry Ellen. This was my job. Let's chat about this soon.

Joe

From: Gadbois, Ellen (NIH/OD) [E] < b6 >
Sent: Friday, July 10, 2020 2:27 PM
To: Wholley, David (FNIH) [T] < b6 >; Adam, Stacey (FNIH) [T] < b6 >; Menetski, Joseph (FNIH) [T] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 > Parker, Ashley (NIH/OD) [E] < b6 >
Subject: RE: REDCap questions

Hi folks,
Just reupping these questions.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, July 7, 2020 7:55 PM

To: Wholley, David (FNIH) [T] b6 Adam, Stacey (FNIH) [T] < b6 >; Menetski, Joseph (FNIH) [T] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 >; Parker, Ashley (NIH/OD) [E] b6 >
Subject: REDCap questions

Hi David and Stacey and Joe,

Following up on our quick conversation earlier, I am hoping to understand better what happens with information entered into the ACTIV compound portal (<https://redcap.ncats.nih.gov/redcap/surveys/index.php?s=DAE87WPTE7&>) that is proprietary, confidential, or trade secret. From talking to folks at NCATS, it sounds like the data is manually entered into an Excel sheet and first goes to people at Deloitte, and then to FNIH. NCATS said that the Deloitte staff are under confidentiality agreements.

Please let me know if I've got that right so far. Then I'm also wondering:

- Does anyone outside of NCATS/NIH have access to the data in REDCap directly, or does it only come to them via Deloitte/FNIH?
- Which groups receive or have received proprietary, confidential, or trade secret information?
- Are those recipients all under confidentiality agreements with regards to the proprietary, confidential, or trade secret information?
- It sounds like there are industry representatives on the agent selection groups—is there any sort of conflict of interest screening for them?

Separate from the confidentiality angle--do you still want the REDCap webpage to talk about vaccine candidates? David you said a while ago that ACTIV won't be talking about vaccines, so I am wondering if it makes sense to have the solicitation still specify vaccine candidates. NCATS folks weren't sure.

Thanks much,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: b6



National Institutes of Health
Turning Discovery Into Health

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: REDCap questions

Sure

From: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Sent: Friday, July 10, 2020 3:29 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: REDCap questions

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Joe

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, July 10, 2020 3:25 PM
To: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: REDCap questions

Thanks. When is good for you? I have time after the 3:30 catchup call if that works.

From: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Sent: Friday, July 10, 2020 3:08 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: REDCap questions

Sorry Ellen. This was my job. Let's chat about this soon.

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From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, July 10, 2020 2:27 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**; Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: REDCap questions

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From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, July 7, 2020 7:55 PM

To: Wholley, David (FNIH) [T] **b6** Adam, Stacey (FNIH) [T] < **b6** >; Menetski, Joseph (FNIH) [T] **b6**
Cc: Culp, Michelle (NIH/OD) [E] **b6** Parker, Ashley (NIH/OD) [E] **b6** >
Subject: REDCap questions

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Thanks much,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
*voice: **b6***
fax: 301-402-0280



National Institutes of Health
Turning Discovery Into Health

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/10/2020 6:22:03 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Tentative: Daily ACTIV Touchbase (FNIH + Deloitte)
Location: see webex below
Start: 7/14/2020 4:30:00 PM
End: 7/14/2020 5:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/10/2020 6:21:50 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: Daily ACTIV Touchbase (FNIH + Deloitte)
Location: see webex below
Start: 7/16/2020 9:00:00 PM
End: 7/16/2020 9:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/26/2020 5:09:00 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte Touchbase (ACTIV)
Location: see webex below
Start: 7/2/2020 7:30:00 PM
End: 7/2/2020 8:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/26/2020 5:08:47 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 6/30/2020 8:30:00 PM
End: 6/30/2020 9:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/25/2020 9:15:16 PM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Fair enough--thanks

From: Martin, Ann (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, June 25, 2020 5:13 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen,

[REDACTED] **b5** [REDACTED], but I am waiting for an update. I will continue to inquire.

Thank you,
Ann

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] **b6** >
Sent: Thursday, June 25, 2020 3:45 PM
To: Martin, Ann (NIH/OD) [E] [REDACTED] **b6**
Cc: Culp, Michelle (NIH/OD) [REDACTED]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

I have my bi-weekly update with FNIH on ACTIV at 5:30 today and I'm sure they will ask again. Do you have any sense of when this is likely to be done? (Do you think there's an issue?) thanks

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, June 22, 2020 7:23 PM
To: Martin, Ann (NIH/OD) [E] [REDACTED] **b6**
Cc: Culp, Michelle (NIH/OD) [REDACTED]
Subject: Re: ACTIV Antitrust Guidelines 6-11-20 for external review

Thanks, Ann. I don't mean to nag but FNIH is asking about the status, so I am just checking in.

Sent from my iPhone

On Jun 16, 2020, at 6:36 PM, Martin, Ann (NIH/OD) [E] [REDACTED] **b6** [REDACTED] wrote:

Hello, Michelle,

We received an email from FNIH counsel Kevin Klock (attached), forwarding a revised draft of the FNIH antitrust policy, [REDACTED] **b5** [REDACTED]. Review of the policy is going up the chain at OGC, including this revised draft. I will stay on top of it and get back to you as soon as I possibly can.

GADB0000000807

Thank you,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892

b6 (main)

b6

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From: Culp, Michelle (NIH/OD) [E] b6
Sent: Tuesday, June 16, 2020 4:30 PM
To: Martin, Ann (NIH/OD) [E] b6 : Gadbois, Ellen (NIH/OD) [E]
< b6
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,
Have you heard anything back from your OGC colleagues on the FNIH draft antitrust policy? If not, I'll check back in later in the week.

Thank you!
Best regards,
Michelle

From: Martin, Ann (NIH/OD) [E] < b6
Sent: Friday, June 12, 2020 8:48 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen,
Thanks for forwarding the FNIH's draft ACTIV antitrust policy. I am consulting on this internally within OGC and will get back to you ASAP. I will be sure to include Michelle. (It is nice to meet you by email, Michelle, and I look forward to working with you).
Best,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892

b6 (main)

b6

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GADB0000000807

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, June 11, 2020 3:40 PM
To: Martin, Ann (NIH/OD) [E] <[REDACTED]> b6
Cc: Culp, Michelle (NIH/OD) [E] [REDACTED] b6
Subject: FW: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,

Here is the draft ACTIV antitrust policy, as explained by David Wholley below. He asks for me to let him know [REDACTED] b5

Copying Michelle, my OSP ACTIV buddy. FYI I will be on leave starting next Tuesday and won't have much email access, so can you please include Michelle in your response?

Thanks,
Ellen

From: Wholley, David (FNIH) [T] [REDACTED] b6
Sent: Thursday, June 11, 2020 3:33 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Cc: Klock, Kevin (FNIH) [T] [REDACTED] b6
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen –

b5

Thanks for your help.

David
<mime-attachment>

From: Gadbois, Elen (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/2/2020 4:12:55 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Declined: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 7/7/2020 8:00:00 PM
End: 7/7/2020 8:30:00 PM
Show Time As: Busy

I have a conflict with another meeting.

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/25/2020 8:44:53 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: CDA question for you

Well I am off of all my calls for now if you want to call me at [REDACTED] b6 I'm going to start dinner prep but will keep my phone handy...

From: Culp, Michelle (NIH/OD) [E] <[REDACTED] b6>
Sent: Thursday, June 25, 2020 3:32 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6>
Subject: RE: CDA question for you

Ellen,
I'm so sorry to be delayed in replying to you. I support you informing LT.

Regarding the table, I don't know of other structured sources of information. I heard that companies are contacting David Wholley and likely NIAID staff and their PIs directly. , I'd suggest adding the kind of information being requested. I added that to as a column. See what you think.

In a similar vein, I'm seeing or hearing about multiple COVID data systems that capture different and sometimes overlapping information. People are asking whether systems will be sustained and how information can be aggregated to be useful for COVID and future work.

I'm having a hard time knowing if Larry and leadership already know about issues and I'm only seeing a small sliver of the big picture.

Do you want to catch up sometime and compare thoughts? I'm available today until our 5:30 FNIH call.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, June 25, 2020 12:58 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED] b6>
Subject: FW: CDA question for you

Hi Michelle,
I am trying to decide what the next move is here. I think either NIH should not be receiving proprietary info etc unless we have thought through how that information is handled, especially when it may go on to FNIH and ACTIV WG members in some form. I don't like to go straight to LT with this, but I don't want these concerns to get dismissed by a non-NIH person before they get to LT. I can follow up with Christine, but this presumably spans multiple WGs. Maybe I just write to LT. But I don't have all the facts. Thoughts?
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, June 24, 2020 3:55 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6 Culp, Michelle (NIH/OD) [E] [REDACTED] b6
Cc: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
Subject: RE: CDA question for you

Thanks, Ashley. I started to make a table to map this out. Michelle, can you take a look at this and let me know if you think we have any further information (or can get more on the NIH side)?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, June 24, 2020 3:11 PM
To: Gadbois, Ellen (NIH/OD) [E] **b6**
Cc: Brodd, Lauren (NIH/OD) [E] **b6** >; Culp, Michelle (NIH/OD) [E] **b6**
Subject: RE: CDA question for you

Hi Ellen,

I thought the answer was NO to confidential/proprietary information being stripped from the submissions. See response from Beth below.

You are correct. That was our original intent, but people have not been good about marking things as confidential or they mark their entire submission as confidential. At this point, I think we need to assume that it's all proprietary/confidential.

Best,
Beth

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, June 24, 2020 2:27 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6** Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: CDA question for you

Dropping Stacey and still setting aside the RedCap stuff...Ashley do you know, or who could tell us, whether confidential/proprietary/trade secret info gets stripped from the submissions to the NIH OD COVID portal before they are passed on to FNIH/ACTIV?

From: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, June 24, 2020 2:20 PM
To: Gadbois, Ellen (NIH/OD) [E] **b6**
Cc: Culp, Michelle (NIH/OD) [E] **b6** >; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Brodd, Lauren (NIH/OD) [E] **b6**
Subject: RE: CDA question for you

Hi Ellen,

For the general WG review, we do not have confidentiality in place. This is why we allow companies to tell us they will only share certain things with CDA.

We have the capability to do this, and we have put CDAs and confidentiality in place for the Agent Selection Committee who are reviewing full company data for the neutralizing antibodies.

I hope this helps.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (301) b6 | Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] b6

Sent: Wednesday, June 24, 2020 2:14 PM

To: Adam, Stacey (FNIH) [T] b6

Cc: Culp, Michelle (NIH/OD) [E] b6 Parker, Ashley (NIH/OD) [E] <a b6 Brodd,

Lauren (NIH/OD) [E] <l. b6 >

Subject: CDA question for you

Hi Stacey,

My NIH OD colleagues and I were talking today about the submissions that come in to the [NIH COVID portal](#), some of which ends up coming to you for consideration by your ACTIV working group. We are wondering if you have had the working group members sign a confidential disclosure agreement or something like that regarding their review of any information that submitters marked as confidential or proprietary or trade secret.

Thanks,

Ellen

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy

Office of Science Policy

Office of the Director

National Institutes of Health

Building 1 Suite 218

voice: b6

fax: 301-402-0280



National Institutes of Health
Turning Discovery Into Health

GADB0000000817

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/24/2020 3:35:33 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte Daily Touchbase (ACTIV)
Location: see webex below
Start: 6/25/2020 9:30:00 PM
End: 6/25/2020 10:00:00 PM
Show Time As. Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/1/2020 9:05:32 PM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
Subject: Re: ACTIV Antitrust Guidelines 6-11-20 for external review

Sure—I am free now if you want to call b6

Sent from my iPhone

On Jul 1, 2020, at 4:56 PM, Martin, Ann (NIH/OD) [E] < b6 > wrote:

Hi, Ellen,

Can we touch base by phone - no reason for concern or anything. I could talk now or tomorrow, anytime except 11:00-11:30.

Thanks,

Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

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From: Gadbois, Ellen (NIH/OD) [E] < b6 >
Sent: Wednesday, July 1, 2020 2:47 PM
To: Martin, Ann (NIH/OD) [E] < b6 >
Cc: Culp, Michelle (NIH/OD) [E] < b6 >
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,

FN.H is asking again about status of the antitrust policy review. Is there anything more I can say?

Thanks,

Ellen

From: Martin, Ann (NIH/OD) [E] < b6 >
Sent: Thursday, June 25, 2020 5:13 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 >
Cc: Culp, Michelle (NIH/OD) [E] < b6 >
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen,

b5 , but I am waiting for an update. I will continue to inquire.

GADB0000000826

Thank you,
Ann

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, June 25, 2020 3:45 PM
To: Martin, Ann (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

I have my bi-weekly update with FNIH on ACTIV at 5:30 today and I'm sure they will ask again. Do you have any sense of when this is likely to be done? (Do you think there's an issue?) thanks

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, June 22, 2020 7:23 PM
To: Martin, Ann (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >
Subject: Re: ACTIV Antitrust Guidelines 6-11-20 for external review

Thanks, Ann. I don't mean to nag but FNIH is asking about the status, so I am just checking in.

Sent from my iPhone

On Jun 16, 2020, at 6:36 PM, Martin, Ann (NIH/OD) [E] <ann. b6 wrote:

Hello, Michelle,

b5

b5 I will stay on top of it and get back to
you as soon as I possibly can.

Thank you,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

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From: Culp, Michelle (NIH/OD) [E] b6
Sent: Tuesday, June 16, 2020 4:30 PM
To: Martin, Ann (NIH/OD) [E] < b6 Gadbois, Ellen (NIH/OD) [E]
b6
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

GADB0000000826

Hi Ann,

Have you heard anything back from your OGC colleagues on

b5

b5 If not, I'll check back in later in the week.

Thank you!

Best regards,

Michelle

From: Martin, Ann (NIH/OD) [E] < > b6

Sent: Friday, June 12, 2020 8:48 AM

To: Gadbois, Ellen (NIH/OD) [E] < > b6

Cc: Culp, Michelle (NIH/OD) [E] < b6

Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen,

Thanks for forwarding

b5

I am consulting on this

internally within OGC and will get back to you ASAP. I will be sure to include

Michelle. (it is nice to meet you by email, Michelle, and I look forward to working with you).

Best,

Ann

Ann D. Martin

Senior Attorney, Office of the General Counsel

HHS, PHD, NIH Branch

31 Center Drive, Bldg. 31, Rm. 2B-50

Bethesda, MD 20892

b6 (main)

An b6

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From: Gadbois, Ellen (NIH/OD) [E] < > b6

Sent: Thursday, June 11, 2020 3:40 PM

To: Martin, Ann (NIH/OD) [E] b6

Cc: Culp, Michelle (NIH/OD) [E] b6

Subject: FW: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,

Here is the draft ACTIV antitrust policy, as explained by David Wholley below. He asks for me to let him know b5

Copying Michelle, my OSP ACTIV buddy. FYI I will be on leave starting next Tuesday and won't have much email access, so can you please include Michelle in your response?

Thanks,

Ellen

From: Wholley, David (FNIH) [T] b6

Sent: Thursday, June 11, 2020 3:33 PM

GADB0000000826

To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Klock, Kevin (FNIH) [T] b6 >
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen –

b5



Thanks for your help.

David
<mime-attachment>

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/7/2020 5:02:30 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 7/7/2020 8:30:00 PM
End: 7/7/2020 9:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/15/2020 9:10:38 PM
To: Godin, Jacquelyn (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc88d464efc34115904f29a975aeeb85-godinja]; Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
CC: Wann, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35a10ade04db43c997fbbc28531571fc-wanneg]; Jessica (NIH/OD) Tucker [E] ([b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]
Subject: FW: AMP MOU Amendment 1 (AMP- [b4])
Attachments: 200612 AMP MOU Amendment 1 (AMP [b4]).docx; 200612 AMP MOU Amendment 1 (AMP- [b4]).pdf; 200122 NIH OD - MOU - AMP FE.pdf

Hi Jackie and Ann,

Can you take a look at proposed amendment to the AMP MOU? The basic idea of not amending the MOU with each new project seems good to me (e.g. there is a gene therapy project with NCATS and FDA coming along), but I don't the tone of the rest. At a quick glance the second provision seems a little heavy-handed to me, but maybe that is standard language now. The 3rd provision sounds like they don't trust us.

In terms of priorities, I think the ACTIV antitrust policy review is more urgent, but I'm passing this along as I'm on leave the rest of this week.

Thanks,
Ellen

From: Appelmans, Eline (FNIH) [T] < [b6] >
Sent: Monday, June 15, 2020 4:54 PM
To: Gadbois, Ellen (NIH/OD) [E] < [b6] >
Cc: Godin, Jacquelyn (NIH/OD) [E] < [b6] > Wholley, David (FNIH) [T] < [b6] > Master, Catherine (FNIH) [T] < [b6] >
Subject: AMP MOU Amendment 1 (AMP- [b4])

Dear Ellen,

b4

Kind Regards,
Eline

Eline Appelmaus, MD, MPH, BMedSci
Program Manager Neuroscience Research Partnerships
Foundation for the National Institutes of Health
Work Cell: **b6** fnih.org
Personal Cell: **b6**
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNHI's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/6/2020 7:00:37 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: FNIH + Deloitte ACTIV Touchbase

Thanks, Cheryl

From: Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**
Sent: Monday, July 6, 2020 2:31 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: FNIH + Deloitte ACTIV Touchbase

I just resent the invite for you

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6

[mailed]
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19. [fnih.org/pandemic](#)



From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, July 6, 2020 2:29 PM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: FNIH + Deloitte ACTIV Touchbase

Hi Cheryl—My schedule has changed and I think I can make this meeting now, but can't figure out how to undo my reply. Could you resent the invitation?

Thanks,
Ellen

-----Original Appointment-----

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, July 2, 2020 12:13 PM
To: Melencio, Cheryl (FNIH) [T]
Subject: Declined: FNIH + Deloitte ACTIV Touchbase
When: Tuesday, July 7, 2020 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: see webex below

I have a conflict with another meeting.

GADB0000000850

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/6/2020 6:49:07 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 7/7/2020 8:00:00 PM
End: 7/7/2020 8:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/1/2020 12:39:16 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte Touchbase (ACTIV)
Location: see webex below
Start: 7/2/2020 9:30:00 PM
End: 7/2/2020 10:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/23/2020 1:51:02 PM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Thanks, Ann. And do you have any thoughts yet on the proposed amendments to the AMP MOU b4 ?
Ellen

From: Martin, Ann (NIH/OD) [E] < b6 >
Sent: Tuesday, June 23, 2020 9:13 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6 >
Cc: Culp, Michelle (NIH/OD) [E] < b6 >
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen,
I hope you enjoyed your time away from the office. I appreciate your checking in, and I am working on getting a status update.
Thanks,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (mam)
b6

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From: Gadbois, Ellen (NIH/OD) [E] <b6 >
Sent: Monday, June 22, 2020 7:23 PM
To: Martin, Ann (NIH/OD) [E] <a b6 >
Cc: Culp, Michelle (NIH/OD) [E] < b6 >
Subject: Re: ACTIV Antitrust Guidelines 6-11-20 for external review

Thanks, Ann. I don't mean to nag but FNIH is asking about the status, so I am just checking in.
Sent from my iPhone

On Jun 16, 2020, at 6:36 PM, Martin, Ann (NIH/OD) [E] < b6 > wrote:

Hello, Michelle,

b5

b5

I will stay on top of it and get back to you as soon as I possibly can.

GADB0000000879

Thank you,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892

b6 (main)
b6

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From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6
Sent: Tuesday, June 16, 2020 4:30 PM
To: Martin, Ann (NIH/OD) [E] <[REDACTED]> b6; Gadbois, Ellen (NIH/OD) [E]
<[REDACTED]> b6
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,
Have you heard anything back from your OGC colleagues on [REDACTED] b5 if not, I'll
check back in later in the week.

Thank you!
Best regards,
Michelle

From: Martin, Ann (NIH/OD) [E] <[REDACTED]> b6
Sent: Friday, June 12, 2020 8:48 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen,
Thanks for forwarding [REDACTED] b5 I am consulting on this internally within
OGC and will get back to you ASAP. I will be sure to include Michelle. (It is nice to meet you by email,
Michelle, and I look forward to working with you).
Best,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892

b6 (main)
b6

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GADB0000000879

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Thursday, June 11, 2020 3:40 PM
To: Martin, Ann (NIH/OD) [E] <[REDACTED]>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]>
Subject: FW: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,

Here is the draft ACTIV antitrust policy, as explained by David Wholley below. He asks for me to let him know [REDACTED]

Copying Michelle, my OSP ACTIV buddy. FYI I will be on leave starting next Tuesday and won't have much email access, so can you please include Michelle in your response?

Thanks,
Ellen

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Thursday, June 11, 2020 3:33 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Cc: Klock, Kevin (FNIH) [T] <[REDACTED]>
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen –

[REDACTED]

Thanks for your help.

David
<mime-attachment>

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/21/2020 8:44:37 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Call #6
Location: <https://fnih.zoom.us/> b6
Start: 7/29/2020 6:30:00 PM
End: 7/29/2020 8:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/21/2020 8:43:42 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Team #6 Pre-call
Location: see webex below
Start: 7/27/2020 8:00:00 PM
End: 7/27/2020 8:30:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/21/2020 7:09:03 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte Daily Touchbase (ACTIV)
Location: see webex below
Start: 6/23/2020 9:00:00 PM
End: 6/23/2020 9:30:00 PM
Show Time As. Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/21/2020 7:08:48 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte Daily Touchbase (ACTIV)
Location: see webex below
Start: 6/25/2020 8:00:00 PM
End: 6/25/2020 8:30:00 PM
Show Time As. Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/23/2020 12:37:22 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Klock, Kevin (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6a4795309e54d3d887b0051aa88183b-klockka]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Michelle heard from OGC in the middle of last week that it was still in review (along with the b5)—I asked them last night for an update.

From: Wholley, David (FNIH) [T] < b6 >
Sent: Monday, June 22, 2020 5:46 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 >
Cc: Klock, Kevin (FNIH) [T] < b6 >
Subject: FW: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ellen – realize you are just back from vacation but when you get the chance could you please update us on where this stands? Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Thursday, June 11, 2020 3:33 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 >
Cc: Klock, Kevin (FNIH) [T] < b6 >
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen –

b5

Thanks for your help.

David

From: Wood, Gretchen (NIH/OD) [E] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=549F390B39D044A885D1E0E1A8F76C1F-WOODGS]

Sent: 6/5/2020 2:05:43 PM

To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Brennan, Patti (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a15fb17e820c4a418b87b86db1dfd6ff-brennanpf]; Norris, Andrea (NIH/CIT) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1f828533385410bb4be4ea63636d1d5-norrisat]; Jerry Sheehan [REDACTED] b6 Gregurick, Susan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e06fcd4c9c5449fb3151183f1adf35e-greguricksk]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Mie Perala [REDACTED] b6 Dina Simon [REDACTED] b6 Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Pfister, Troy (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70d843c03f864b5cb60b8f2f5f7a313c-ptroy]; Diebete, Ariana (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3ea9c08c9e24bdebe268dfb54a1bef7-diebeteaa]; Abdullah, Sharon (NIH/CIT) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4eba9c16b53c4b11a8f3ba23a651a579-willis]

Subject: Meeting request on behalf of Dr. Francis Collins

Good morning,

Please respond to confirm your/your principal's availability for the following date and times:

DATE:	Wednesday, June 10, 2020
TIME:	12:15 PM-1:00 PM ET; or 3:00 PM-3:45 PM ET
PLACE:	Via WebEx
PURPOSE:	Takeda Pharmaceuticals/NIH/FNIH discussion on data sharing
PARTICIPANTS:	Francis Collins Larry Tabak Andrew Plump Anne Heatherington Maria Freire David Wholley Chris Austin Patti Brennan Andrea Norris Jerry Sheehan Susan Gregurik Mike Kurilla

Ellen Gadbois Michelle Culp

Please provide availability for both times and we will send out a WebEx to confirm. Thanks very much.

Best wishes,

Gretchen

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/12/2020 5:19:55 PM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: Fwd: ACTIV Draft Antitrust Guidelines

FYI

Sent from my iPhone

Begin forwarded message.

From: "McGarey, Barbara (NIH/OD) [C]" <[REDACTED]> **b6**
Date: June 12, 2020 at 1:16:15 PM EDT
To: "Godin, Jacquelyn (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: ACTIV Draft Antitrust Guidelines

Hi Jackie,

I understand that David Wholly of FNIH sent [REDACTED] **b5** to Ellen for NIH review, and that Ellen has forwarded them to OGC. Just wanted to let you both know that I was involved in the FNIH legal review and would be happy to provide any background and/or answer any questions that arise during your review, if I am able. This has certainly been an interesting and fast moving project.

Cheers,

Barb

Barbara McGarey, J.D.
Consultant
Foundation for the NIH

[REDACTED] **b6**

[REDACTED] **b6**

[REDACTED] **b6**

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/12/2020 1:16:12 PM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Thanks, Ann.

From: Martin, Ann (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, June 12, 2020 8:48 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen,

Thanks for forwarding [REDACTED] **b5** I am consulting on this internally within OGC and will get back to you ASAP. I will be sure to include Michelle. (It is nice to meet you by email, Michelle, and I look forward to working with you).

Best,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B 50
Bethesda, MD 20892

b6 (main)
b6

NOTICE: This e-mail message may contain information that is protected, privileged, or confidential. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this e-mail message in error, please notify the sender immediately.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** >
Sent: Thursday, June 11, 2020 3:40 PM
To: Martin, Ann (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FW: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,

Here is the draft ACTIV antitrust policy, as explained by David Wholley below. He asks for me to let him know [REDACTED] **b5**

Copying Michelle, my OSP ACTIV buddy. FYI I will be on leave starting next Tuesday and won't have much email access, so can you please include Michelle in your response?

Thanks,
Ellen

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, June 11, 2020 3:33 PM

GADB0000000945

To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Klock, Kevin (FNIH) [T] b6 >
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen –

b5

Thanks for your help.

David

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/5/2020 7:11:31 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: ATTENTION: ACTIV Communication Items
Attachments: ACTIV Social Media 6.2.20 ap.docx, NIH OCPL_COVID-19 ACTIV TalkingPts 06.02.20 ap.pptx

Just FYI as I look through my unread email from the week.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, June 2, 2020 6:48 PM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]> Collins, Francis (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED]> Fine, Amanda (NIH/OD) [E] <[REDACTED]> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> Hallett, Adrienne (NIH/OD) [E] <[REDACTED]> Higgins, Lauren (NIH/OD) [E] <[REDACTED]> Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> Brodd, Lauren (NIH/OD) [E] <[REDACTED]> Meltzer, Abbey (FNIH) [T] <[REDACTED]> Gorman, Greta (FNIH) [T] <[REDACTED]>
Subject: RE: ATTENTION: ACTIV Communication Items

Hi Renate,

Looks great! Please see attached comments on the social media language and slides given recent updates.

Thank you,
Ashley

From: Myles, Renate (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, June 2, 2020 5:58 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED]> Fine, Amanda (NIH/OD) [E] <[REDACTED]> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> Hallett, Adrienne (NIH/OD) [E] <[REDACTED]> Higgins, Lauren (NIH/OD) [E] <[REDACTED]> Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> Brodd, Lauren (NIH/OD) [E] <[REDACTED]> Meltzer, Abbey (FNIH) [T] <[REDACTED]> Gorman, Greta (FNIH) [T] <[REDACTED]>
Subject: ATTENTION: ACTIV Communication Items

Good evening:

I wanted to share a few items for your awareness and attention:

- 1) Tomorrow we will push the new designs of the ACTIV website and will promote the webpage via an NIH.gov homepage slide and social media. The social media language emphasizes that ACTIV aims to accelerate the development of vaccines and treatments for COVID-19 by streamlining administrative processes while maintaining rigorous safety standards. The homepage slide and social media language are attached.
- 2) Tomorrow, we expect the NYT to run a story on the five candidates selected by Operation Warp Speed. NYT says they've verified the five candidates from numerous sources, although HHS has said on the record that they will

not confirm involvement in the initial group of vaccines unless a company is bound by fiduciary requirements to report contractual agreements. From what I can find, HHS has confirmed the following vaccine candidates: Jansen, Moderna, and AstraZeneca under OWS.

- 3) We've received numerous requests from NIH Institutes and Centers for general ACTIV slides that they could incorporate into their slide decks for Councils, etc. We've developed the attached slide deck using top line talking points. The graphic style mimics the new web graphics. Please let us know if you have any concerns with the slides or the messaging.

Best,
Renate

Renate Myles, MBA

Deputy Director for Public Affairs

Office of Communications and Public Affairs

National Institutes of Health

Phone: 301-401-6060
b6

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 5/21/2020 3:27:23 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: RE: All of Us program and vaccine trials?

Thanks Karen

From: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, May 21, 2020 11:26 AM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: All of Us program and vaccine trials?

This is on my list to do. And I will do it now so keep your eyes open for a number of invites.
Apologies for the delay.
Karen

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, May 21, 2020 11:21 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** >; Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: All of Us program and vaccine trials?

Karen,
May I please be added to the Clinical Trial Capacity WG calls, too? Thank you.

Best regards,
Michelle

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, May 21, 2020 11:13 AM
To: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: All of Us program and vaccine trials?

Hi Karen,
I just wanted you to know I haven't seen the invitation for tomorrow's meeting yet. I know you all are working like crazy, so just didn't want that to get overlooked.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, May 20, 2020 9:43 PM
To: Tountas, Karen (FNIH) [T] <[REDACTED]> **b6**
Cc: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: Re: All of Us program and vaccine trials?

Sounds good

Sent from my iPhone

On May 20, 2020, at 7:46 PM, Tountas, Karen (FNIH) [T] [b6] wrote:

Hi Ellen,

The All of Us team will be presenting to the Clinical Trial Capacity WG on this Friday, May 22 at 9 am eastern US time. I'll forward the invite to you and hope that you will be able to join the call

Best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

[b6] fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
<image001.jpg>

<image002.jpg>

<image003.jpg>

<image004.jpg>

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 20, 2020 5:32 PM
To: Gadbois, Ellen (NIH/OD) [E] <[b6]>
Cc: Tountas, Karen (FNIH) [T] [b6]
Subject: FW: All of Us program and vaccine trials?

Ellen, here is a bit of correspondence on the All of Us stuff. Karen can bring you up to speed and tell you whether further help is needed.

From: Tountas, Karen (FNIH) [T] [b6]
Sent: Monday, May 18, 2020 6:14 PM
To: Collins, Francis (NIH/OD) [E] [b6] >; Denny, Joshua (NIH/OD) [E] <[b6]>
Cc: Wholley, David (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: All of Us program and vaccine trials?

Dear Francis,

Your email is very timely. The Clinical Trial Capacity Working Group (CTC WG) had very briefly brought up the ALL of Us program very early in their discussions, but had, at that time, focused intently on generating a CRO/SMO/Network Site inventory for therapeutics. And, now, vaccines trials are on the horizon so...

Josh – It would be very interesting to the CTC WG members to hear about the program and to explore with you how ACTIV might harness its potential for vaccine trials. Would you have time to talk with the WG? We meet on Tuesdays and Fridays at 9 am via Zoom. Would this Friday, May 22, or next Tuesday, May 26, work for you? Many thanks for considering this opportunity.

Cheers!

GADB0000000975

Karen

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Monday, May 18, 2020 5:59 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> Tountas, Karen (FNIH) [T] <[REDACTED]>
Adam, Stacey (FNIH) [T] <[REDACTED]>
Cc: Denny, Joshua (NIH/OD) [E] <[REDACTED]>
Subject: All of Us program and vaccine trials?

Hi David, Karen, and Stacey,

A couple of weeks ago I brought up the idea of exploring the possibility of enlisting the *All of Us* program as a source of volunteers for COVID-19 vaccine trials. With ~240,000 motivated and highly diverse participants, pre-consented for recontact, and located all over the country including areas where COVID-19 is actively spreading, this seems like an interesting opportunity. And there are repository biospecimens available for them too.

Did that discussion go anywhere? Josh Denny (cc'd here), the CEO of *All of Us*, would be glad to engage with you about specifics if that would help.

Francis

From: Gadbois, Elen (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 5/28/2020 4:17:47 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: Accepted: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Location: <https://fnih.zoom.us/> **b6**
Start: 6/2/2020 1:00:00 PM
End: 6/2/2020 2:00:00 PM
Show Time As: Busy

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/5/2020 6:06:26 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte Daily Touchbase (ACTIV)
Location: see webex below
Start: 6/9/2020 7:30:00 PM
End: 6/9/2020 8:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/11/2020 7:36:46 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Klock, Kevin (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6a4795309e54d3d887b0051aa88183b-klockka]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Got it. I'm sending it to our OGC now—I already gave them a heads up that this would be coming

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, June 11, 2020 3:33 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Klock, Kevin (FNIH) [T] <[REDACTED]> **b6**
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen —

b5

Thanks for your help.

David

From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/5/2020 6:06:17 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: FNIH + Deloitte Daily Touchbase (ACTIV)
Location: see webex below

Start: 6/11/2020 6:30:00 PM
End: 6/11/2020 7:00:00 PM
Show Time As: Busy

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/5/2020 5:33:53 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in

Oh this is just one of the few places where I have some clue as to who could be involved.

-----Original Message-----

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]>
Sent: Friday, June 5, 2020 10:28 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Subject: RE: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in

Thank you for sending this! You have good OD-sense!

-----Original Message-----

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Friday, June 5, 2020 9:57 AM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]>
Subject: Fw: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in

Hope this is OK. Jump in if I got stuff wrong

-----Original Message-----

From: Jorgenson, Lyric (NIH/OD) [E] <[REDACTED]>
Sent: Friday, June 5, 2020 9:52 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> Tucker, Jessica (NIH/OD) [E] <[REDACTED]>
Subject: RE: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in

Oof

I'm looping in Carrie. I think she and I need to discuss who would be the right person to put on this.

-----Original Message-----

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Friday, June 5, 2020 9:48 AM
To: Jorgenson, Lyric (NIH/OD) [E] <[REDACTED]>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> Tucker, Jessica (NIH/OD) [E] <[REDACTED]>
Subject: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in

Lyric--Jessica will bring this to your attention later but this is likely to be moving super fast. Bottom line: I think SciDASH needs to be brought in to help advise LT on an effort he is leading to figure out platform(s) and rules for data sharing in ACTIV. I can help provide context and Michelle understands a lot here, but we need someone who can speak to any application of NIH policy on data sharing & privacy for data from the ACTIV partners. At least some of the data will be from NIH-funded research. People are trying to sort out the IT capabilities of various data sharing platforms for both summary and individual level data, and what data sharing and privacy rules apply. Lots of cooks in the kitchen already but someone needs to authoritatively sort out NIH policy on privacy and data sharing. Also there is discussion about whether CT.gov has a role--seems like no one thinks CT.gov is useful, and FC wants to know why not, and FNIH thinks this is an NIH thing to sort out. I don't really understand the policy landscape. Michelle (cc'd) has a better grip on the CT.gov situation and the networks likely to be generating data, but we both think SciDASH needs to be part of this. If Taunton is involved, he could be thinking about HIPPA too.

See emails from FC and Andy Plump (Takeda) below.

Things are moving really fast. Big monoclonal antibody summit Tuesday and everyone is trying to get ducks in a row before then.

-----Original Message-----

GADB0000000989

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Thursday, June 4, 2020 5:23 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6 : Gadbois, Ellen (NIH/OD) [E]
<gadboisel@od.nih.gov>
Subject: FW: Data-Sharing

Taking the liberty of sending you this. I also emailed my thoughts to Larry.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew <[REDACTED]> b6 Paul Stoffel <[REDACTED]> b6 Heatherington, Anne
<[REDACTED]> b6
Cc: Mikael Dolsten MD PhD <[REDACTED]> b6 wholley, David (FNIH) [T] <[REDACTED]> b6
Tabak, Lawrence (NIH/OD) [E] <lawrence.[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> b6 .gov>
Subject: RE: Data-Sharing

Hi Andy,

Thanks for your leadership on these critical data sharing issues -- and yes, a group of us from NIH/FNIH would very much like to meet with you, Anne, and any others that you think would assist the conversation. I have already asked my principal Deputy, Dr. Larry Tabak, to assemble the right NIH group to take part in this conversation, and I will count on David to figure out who should attend from FNIH.

One of the items that I know the group will want to know more about is the Gates Accelerator -- it's been hard to get a sense of the architecture and ease of use. Is there a beta test model available that we could try out?

Best, Francis

-----Original Message-----

From: Plump, Andrew <[REDACTED]> b6
Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Paul Stoffel <[REDACTED]> b6
Heatherington, Anne <[REDACTED]> b6
Cc: Mikael Dolsten MD PhD <[REDACTED]> b6 wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: Data-Sharing

Hi Francis and Paul,

Terrific ACTIV leadership meeting yesterday. Remarkable progress.

Following up on the HEVER dialogue on data-sharing. I know you are fully on board with the need for essentially real-time data sharing of emerging clinical trial data, and there is a team that has identified a framework that should work for the NIH. While there may be arcane US government provisions to which we are not aware, the privacy considerations are at least as stringent within industry, and essentially all companies have agreed to the framework Anne presented, so I do not imagine roadblocks.

My suggestion is that Anne and members of the data sharing group meet with you, David, and/or whomever else you would suggestion from NIH/ACTIV to bring you up to speed and figure out a path forward.

Thanks,
Andy

Sent from my iPad

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From: Gadbois, El en (N/H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/11/2020 7:24:28 PM
To: Adam, Stacey (FNIH) [TI [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Declined: ACTIV TX-Clinical Working Group Meeting #11
Location: <https://fnih.zoom.us/j/> b6
Start: 6/18/2020 5:00:00 PM
End: 6/18/2020 6:00:00 PM
Show Time As. Busy

On annual leave

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 1/15/2021 3:46:04 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Dolsten, Mikael [b6]
CC: Kamphaus, Tania (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af5446a0db6a49499cfe3613cab9c610-kamphaustn]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: Short presentation on AMP Common Metabolic Disorders (AMP CMD) tomorrow

The AMP CMD slides look fine, and many thanks to Mikael for agreeing to do the "ask".

It's also fine with me to distribute the text version to Hever in advance of the meeting.

Francis

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Thursday, January 14, 2021 8:20 PM
To: Dolsten, Mikael <[b6]>
Cc: Collins, Francis (NIH/OD) [E] <[b6]> Kamphaus, Tania (FNIH) [T] <[b6]> Parker, Ashley (NIH/OD) [E] <[b6]> Gadbois, Ellen (NIH/OD) [E] <[b6]>
Subject: Short presentation on AMP Common Metabolic Disorders (AMP CMD) tomorrow
Importance: High

Hi Mikael.

First of all, Tania Kamphaus here on our FNIH team tells me that we have recently been given at least a verbal signal that Pfizer intends to support the AMP CMD effort. Thank you so much for your support!

As you may recall, on our last AMP EC meeting we agreed that the AMP CMD effort would be brought to discussion at the next Hever meeting with the idea of seeing if we can rally a few additional funders and move it forward toward launch. I understand that the meeting has been scheduled for this Tuesday, January 19, and that slides have been requested to be sent in by tomorrow morning. To that end, we have put together the attached slide deck. Francis (copied) can probably present some of the upfront science, but the final (fundraising) slide is not something he can really talk about. Would you be willing to at least split duties on this with him? I think we'd be happy with whatever division of labor you and Francis would agree to; I know Francis will be talking about ACTIV as well.

I have also attached a brief text description of the project which I will ask the Hever folks to distribute prior to the meeting, if OK with you both. Please let me know any questions or changes you'd like to the slide deck.

Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
[b6] fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852





From: Read, Sarah (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=527B160038004A199AE6E0BAC2226099-READSA]
Sent: 1/14/2021 7:10:17 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: Re: Ivermectin study: NCT04405843

Thank you!

From: "Culp, Michelle (NIH/OD) [E]" b6 y>
Date: Thursday, January 14, 2021 at 1:02:56 PM
To: "Read, Sarah (NIH/NIAID) [E]" b6 , "Adam, Stacey (FNIH) [T]" b6
Cc: "Gadbois, Ellen (NIH/OD) [E]"
Subject: FW: Ivermectin study: NCT04405843

No results reported yet.
More info on checking on results and another ivermectin study below....

From: Robbins, Alison (NIH/NLM/NCBI) [E] < b6
Sent: Thursday, January 14, 2021 12:23 PM
To: Culp, Michelle (NIH/OD) [E] < b6 Williams, Rebecca (NIH/NLM/NCBI) [E] < b6
Cc: Fine, Anna (NIH/NLM/NCBI) [E] < b6 Gadbois, Ellen (NIH/OD) [E] < b6
Subject: RE: Ivermectin study: NCT04405843

Hi Michelle,

Results have not, yet, been submitted for NCT04405843. There is a way to know whether results have been submitted by looking at the study page on the public site. The "No Results Posted" tab (on the main study page) will change to "Results Submitted" and include the submission date and review cycle(s).

Also, Becky noted that she was aware of other studies, with results, for ivermectin, if those are of any interest: <https://clinicaltrials.gov/ct2/results?cond=COVID-19&term=ivermectin>

Thank you!

Alison

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Thursday, January 14, 2021 11:50 AM
To: Williams, Rebecca (NIH/NLM/NCBI) [E] b6
Cc: Robbins, Alison (NIH/NLM/NCBI) [E] b6 >; Fine, Anna (NIH/NLM/NCBI) [E] < b6
Gadbois, Ellen (NIH/OD) [E] b6
Subject: Ivermectin study: NCT04405843

Hi Becky,

I'm not sure who in your group to ask, so please advise or pass this on.

On the ACTIV Leadership call, there was discussion about ivermectin as a therapy for COVID. NIH has also received inquiries about NIH's plans to include ivermectin in clinical trials.

There is a study ([NCT04405843](#)) in Colombia that just met its primary complete date (Dec 21, 2020). Is there any chance results information has been received by NLM yet?

Thanks!

Michelle

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/27/2021 6:18:49 PM
To: Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Mendelson, Jesse [b6] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [b6] Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: FNIH + Deloitte ACTIV Touchbase

And mine was COVER (COronavirus Variant Examination and Response)

From: Hawk, Harrison <b6>
Sent: Wednesday, January 27, 2021 1:02 PM
To: Melencio, Cheryl (FNIH) [T] <b6> Adam, Stacey (FNIH) [T] <b6> Margaret Anderson
<b6> Appell, Evan <b6> Chen, Helen <b6>
Connelly, Sarah <b6> Gonzalez, Nina <b6> Mendelson, Jesse
<b6> Menetski, Joseph (FNIH) [T] <b6> Nasr, Hana <b6>
Santos, Michael (FNIH) [T] <b6> Sorosa, Alex <b6> Stratton, Benjamin
<b6> btolman <b6> Wachtel, Jonathan <b6>
Wholley, David (FNIH) [T] <b6> Culp, Michelle (NIH/OD) [E] <b6> Gadbois, Ellen
(NIH/OD) [E] <b6>
Subject: RE: FNIH + Deloitte ACTIV Touchbase

Hi all,

For those who are curious, here are the group names that were floated to David:

PREPARE
(Predicting Rapid Emergence of Pathogenicity And Resistance)

PROTECT

(Predicting Resistance Or Therapeutic Escape of new Coronavirus Threats)

'TRAPS' or 'TRAP-CoV'

(Tracking Resistance And Pathogenicity of SARS-CoV-2)

Thanks!

Harrison

Harrison Hawk

Deloitte Consulting LLP

b6

www.deloitte.com

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6

Sent: Wednesday, January 13, 2021 9:32 AM

To: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen Q.; Connelly, Sarah; Gonzalez, Nina, Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Nasr, Hana; Santos, Michael (FNIH) [T]; Sorosa, Alex David; Stratton, Benjamin; Tolman, Brett; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]

Subject: FNIH + Deloitte ACTIV Touchbase

When: Wednesday, January 27, 2021 12:00 PM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: see webex be ow

Join Webex meeting

Meeting number (access code): [REDACTED] b6 Meeting password: [REDACTED] b6

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Dial [REDACTED] b6

You can also dial [REDACTED] b6 8 and enter your meeting number Tap to join from a mobile device (attendees only)
[REDACTED] b6 ## Call-in toll number (US/Canada)

Join by phone

[REDACTED] b6 Call-in toll number (US/Canada)

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Configure meeting

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: Ivermectin study: NCT04405843

Thanks, Michelle!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct **b6** Mobile: **b6**

From: Culp, Michelle (NIH/OD) [E] <**b6**>
Sent: Thursday, January 14, 2021 1:03 PM
To: Read, Sarah (NIH/NIAID) [E] <**b6**> Adam, Stacey (FNIH) [T] <**b6**>
Cc: Gadbois, Ellen (NIH/OD) [E] <**b6**>
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Sent: Thursday, January 14, 2021 12:23 PM
To: Culp, Michelle (NIH/OD) [E] **b6** Williams, Rebecca (NIH/NLM/NCBI) [E]
<[w](#)> **b6**
Cc: Fine, Anna (NIH/NLM/NCBI) [E] **b6** >; Gadbois, Ellen (NIH/OD) [E] **b6**
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Thank you!

Alison

From: Culp, Michelle (NIH/OD) [E] **b6**
Sent: Thursday, January 14, 2021 11:50 AM

GADB0000004040

To: Williams, Rebecca (NIH/NLM/NCBI) [E] b6
Cc: Robbins, Alison (NIH/NLM/NCBI) [E] < b6 >; Fine, Anna (NIH/NLM/NCBI) [E] b6
Gadbois, Ellen (NIH/OD) [E] b6
Subject: Ivermectin study: NCT04405843

Hi Becky,
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Thanks!
Michelle

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 2/1/2021 4:50:30 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [b6 Margaret Anderson [b6 Appell, Evan [b6 Chen, Helen [b6 Connelly, Sarah [b6 Gonzalez, Nina [b6 Hawk, Harrison [b6]; Mendelson, Jesse b6 Menetski, Joseph (FNIH) [T] [b6 Nasr, Hana [b6 Sorosa, Alex [b6 Stratton, Benjamin [b6 Tolman, Brett [b6 Wachtel, Jonathan [b6 Wholley, David (FNIH) [T] b6 ; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] b6 b6
CC: Santos, Michael (FNIH) [T] [b6 Bailey-Burke, Christian [b6
Subject: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 2/12/2021 6:00:00 PM
End: 2/12/2021 6:30:00 PM
Show Time As: Tentative

Required Attendees: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T], Anderson, Margaret; Appel, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; b6
Optional Attendees: Santos, Michael (FNIH) [T], Bailey-Burke, Christian

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Sent: 2/1/2021 4:47:56 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [b6 Margaret Anderson [b6 Appell, Evan [b6 Chen, Helen [b6 Connelly, Sarah [b6 Gonzalez, Nina [b6 Hawk, Harrison [b6]; Mendelson, Jesse [b6 Menetski, Joseph (FNIH) [T] [b6 Nasr, Hana [b6 Sorosa, Alex [b6 Stratton, Benjamin [b6 Tolman, Brett [b6 Wachtel, Jonathan [b6 Wholley, David (FNIH) [T] [b6]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [b6 Dally, Nicolle [b6
CC: Santos, Michael (FNIH) [T] [b6 Bailey-Burke, Christian [b6
Subject: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 2/10/2021 10:00:00 PM
End: 2/10/2021 10:30:00 PM
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Required Attendees: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appel, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Dally, Nicolle
Optional Attendees: Santos, Michael (FNIH) [T]; Bailey-Burke, Christian

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Sent: 8/21/2020 7:55:18 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [b6 Alvarez, Rosa [b6 Anderson, Margaret [b6 Chen, Helen [b6 Elsaid, Olivia [b6 Gonzalez, Nina [b6 Hawk, Harrison [b6 Menetski, Joseph (FNIH) [T] [b6 Stratton, Benjamin [b6 btolman [b6 Wachtel, Jonathan [b6 Wholley, David (FNIH) [T] [b6 Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [b6
CC: Tountas, Karen (FNIH) [T] [b6 Santos, Michael (FNIH) [T] [b6
Subject: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 8/28/2020 6:30:00 PM
End: 8/28/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]
Optional Attendees: Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]

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Sent: 8/21/2020 7:53:09 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [b6 Alvarez, Rosa [b6 Anderson, Margaret [b6 Chen, Helen [b6 Elsaid, Olivia [b6 Gonzalez, Nina [b6 Hawk, Harrison [b6 Menetski, Joseph (FNIH) [T] [b6 Stratton, Benjamin [b6 btolman [b6 Wachtel, Jonathan [b6 Wholley, David (FNIH) [T] [b6 Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [b6
CC: Tountas, Karen (FNIH) [T] [b6 Santos, Michael (FNIH) [T] [b6
Subject: FNIH +Deloitte ACTIV Touchbase
Location: see webex below
Start: 8/26/2020 8:30:00 PM
End: 8/26/2020 9:00:00 PM
Show Time As: Tentative

Required Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]
Optional Attendees: Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]

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Sent: 6/5/2020 5:53:55 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [b6 Alvarez, Rosa [b6 Anderson, Margaret [b6 Chen, Helen [b6 Elsaid, Olivia b6 ; Gonzalez, Nina [n ngonza b6 James, Stephanie (FNIH) [T] [b6 ; Menetski, Joseph (FNIH) [T] b6 Santos, Michael (FNIH) [T] [b6 Stratton, Ben [b6 Tolman, Brett [b6 Tountas, Karen (FNIH) [T] [b6 ; Wachtel, Jonathan b6 Wholley, David (FNIH) [T] [b6 Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] b6

Subject: FNIH + Deloitte Daily Touchbase (ACTIV)

Location: see webex below

Start: 6/11/2020 8:30:00 PM

End: 6/11/2020 9:00:00 PM

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Required Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

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Sent: 8/18/2020 2:55:48 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wholley, David (FNIH) [T] [b6 Menetski, Joseph (FNIH) [T] b6 Adam, Stacey (FNIH) [T] [b6 Collins, Francis (NIH/OD) [E] [b6 Tabak, Lawrence (NIH/OD) [E] [b6 Parker, Ashley (NIH/OD) [E] [b6 Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboise]; Culp, Michelle (NIH/OD) [E] [b6]; Alvarez, Rosa [b6 Anderson, Margaret [b6 Chen, Helen [b6 Elsaid, Olivia [b6 Gonzalez, Nina [b6 Hawk, Harrison [b6 Santos, Michael (FNIH) [T] [b6 Stratton, Benjamin [b6 Tolman, Brett [b6 Wachtel, Jonathan [b6], Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
CC: Wood, Gretchen (NIH/OD) [E] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6 Appell, Evan [b6]
Subject: Pre-Call for ACTIV Leadership Call
Location: see webex below
Start: 9/21/2020 8:00:00 PM
End: 9/21/2020 8:30:00 PM
Show Time As: Busy

Required Attendees: Melencio, Cheryl (FNIH) [T]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Appell, Evan

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Sent: 12/11/2020 7:43:42 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [b6 Margaret Anderson [b6 Appell, Evan [b6 Chen, Helen Q [b6 Connelly, Sarah [b6 Gonzalez, Nina [b6 Hawk, Harrison [b6]; Mendelson, Jesse [b6 Menetski, Joseph (FNIH) [T] [b6 Nasr, Hana [b6 Santos, Michael (FNIH) [T] [b6 Sorosa, Alex David [b6 Stratton, Benjamin [b6 btolman [b6 Tountas, Karen (FNIH) [T] [b6 Wachtel, Jonathan [b6 Wholley, David (FNIH) [T] [dwhol [b6 Culp, Michelle (NIH/OD) [E] [b6 Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: FNIH + Deloitte ACTIV Touchbase
Location: see webex below

Start: 1/6/2021 5:00:00 PM
End: 1/6/2021 5:30:00 PM
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Required Attendees: Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Nasr, Hana; Santos, Michael (FNIH) [T]; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]

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Sent: 8/28/2020 7:17:37 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [b6 Alvarez, Rosa [b6 Anderson, Margaret [b6 Chen, Helen [b6 Elsaid, Olivia b6 ; Gonzalez, Nina [b6 Hawk, Harrison [b6 Menetski, Joseph (FNIH) [T] [b6 Stratton, Benjamin [b6 btolman b6 ; Wachtel, Jonathan b6 Wholley, David (FNIH) [T] [b6 Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [michel b6
CC: Santos, Michael (FNIH) [T] [b6 Tountas, Karen (FNIH) [T] [ktountas@fnih.org]
Subject: FNIH + Deloitte ACTIV Touchbase
Location: see webex below
Start: 9/2/2020 1:00:00 PM
End: 9/2/2020 1:30:00 PM
Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]
Optional Attendees: Santos, Michael (FNIH) [T]; Tountas, Karen (FNIH) [T]

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 5/18/2020 9:07:02 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Meet to discuss new liaison roles

Right. That will flow from whatever it is I'm needed to do, which we can discuss that Wednesday. Thanks

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Monday, May 18, 2020 4:43 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6** Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Meet to discuss new liaison roles

We can wait till our orientation but one thing we will want to discuss is what meetings you want to/should attend.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, May 18, 2020 3:54 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: Meet to discuss new liaison roles

That's very helpful—thanks.

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Monday, May 18, 2020 2:05 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** Melencio, Cheryl (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: Meet to discuss new liaison roles

Sure. I've been so busy I forgot to send the materials. Here are slides from our last several meetings. The "daily update" includes some of the near term meetings; Cheryl can give the schedule for the others. I have also attached the full rosters for the working groups. Cheryl, can you also please send the list of the FNIH/Deloitte support team members? Thanks

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, May 18, 2020 1:36 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Meet to discuss new liaison roles

Hi David,

I hope that you and your family is well.

I'm just checking to see if there are any materials ready for Michelle and me to review before Wednesday. I'm particularly interested in what the schedule looks like for the various working groups. I am not totally sure what I'll be doing as part of this, but it would be good to know about any key dates.

Thanks very much,

Ellen

From: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, May 13, 2020 2:28 PM
To: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** >; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** >; Burrus-Shaw, Cyndi (NIH/OD) [E] <[REDACTED]> **b6** >; Simon, Dina (NIH/OD) [C] <[REDACTED]> **b6** >; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** >; Santos, Michael (FNIH) [T] <[REDACTED]> **b6** >; Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6** >; Tountas, Karen (FNIH) [T] <[REDACTED]> **b6** >; Freire, Maria (FNIH) [T] <[REDACTED]> **b6** >; James, Stephanie (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: Meet to discus new liaison roles

Excellent news, Larry! Welcome aboard to Michelle and Ellen. I think it would make sense for us to include my four key project leads: Stacey Adam, Joe Menetski, Karen Tountas, and Mike Santos on the call so we can hit the ground running. OK for me to send ahead some materials, like the slides and notes from the last LT meeting, to assist in getting them oriented? Or are you sharing info with them in advance of the call? Cheryl Melencio can arrange schedules on our end.

Many thanks,
David

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 13, 2020 1:31 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** >; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** >; Burrus-Shaw, Cyndi (NIH/OD) [E] <[REDACTED]> **b6** >; Simon, Dina (NIH/OD) [C] <[REDACTED]> **b6** >
Subject: Meet to discus new liaison roles

David,

As you discussed with Francis, Michelle Culp and Ellen Gadbois stand ready to assist with enhancing communications/actions between NIH and FNIH for the ACTIV program. Francis, Carrie, and I have discussed, and for the purpose of this activity Michelle and Ellen will use me as their point of contact at NIH.

I would appreciate ho ding an initial meeting for the three of us with you and any other members of your team you wish to include to scope out initial activities etc. A member of my team will reach out to set up a time.

Best wishes,
Larry

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 5/20/2020 11:13:43 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tolman, Brett [REDACTED]
Subject: Re: ACTIV Introduction

Thanks

Sent from my iPhone

On May 20, 2020, at 6:13 PM, Culp, Michelle (NIH/OD) [E] <[REDACTED]> wrote:

Can we include Ellen, if she's available and interested?

Ellen, I asked Adam, Karen and Stacey for an overview of their WGs.

-Michelle

From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Wednesday, May 20, 2020 5:54 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> Tountas, Karen (FNIH) [T] <[REDACTED]> Santos, Michael (FNIH) [T] <[REDACTED]>
Cc: Tolman, Brett <[REDACTED]>
Subject: RE: ACTIV Introduction

Thanks, all!

Let's do tomorrow at 5pm then, on the off hope that may be we would all get to call it and early Friday on the holiday weekend?

I will send an invite to this group. Karen, I am going to invite Elizabeth, do you want me to invite Jonathan?

Thanks,
STacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] | Mobile: [REDACTED]

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 20, 2020 5:21 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** ; Tountas, Karen (FNIH) [T] <[REDACTED]> **b6** Santos,
Michael (FNIH) [T] <[REDACTED]> **b6**
Cc: Tolman, Brett **b6**
Subject: RE: ACTIV Introduction

Both work for me, too.
Stacey, your day sounds busier than mine, so please pick what's easier for you.
-Michelle

From: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, May 20, 2020 3:43 PM
To: Tountas, Karen (FNIH) [T] **b6** >; Santos, Michael (FNIH) [T] **b6**
Culp, Michelle (NIH/OD) [E] **b6**
Cc: Tolman, Brett **b6**
Subject: RE: ACTIV Introduction

Thanks, Karen and Mike.

Michelle, please just let me know what will work for you.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: **b6** | Mobile: **b6**

From: Tountas, Karen (FNIH) [T] **b6**
Sent: Wednesday, May 20, 2020 3:39 PM
To: Santos, Michael (FNIH) [T] **b6** Adam, Stacey (FNIH) [T] **b6** Culp,
Michelle (NIH/OD) [E] **b6** >
Cc: Tolman, Brett **b6**
Subject: RE: ACTIV Introduction

Either work for me as well.

From: Santos, Michael (FNIH) [T] **b6**
Sent: Wednesday, May 20, 2020 3:38 PM
To: Adam, Stacey (FNIH) [T] **b6** >; Culp, Michelle (NIH/OD) [E] **b6**
Tountas, Karen (FNIH) [T] **b6**
Cc: Tolman, Brett <[REDACTED]> **b6**
Subject: RE: ACTIV Introduction

Either works for me – thanks!

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Adam, Stacey (FNIH) [T] b6
Sent: Wednesday, May 20, 2020 3:31 PM
To: Culp, Michelle (NIH/OD) [E] < b6 >; Santos, Michael (FNIH) [T] b6
Cc: Tolman, Brett b6 >
Subject: RE: ACTIV Introduction

Hi All,

Could I interest any one in 4-5pm on Friday? As it is my only truly open time where I would not have to move another meeting. Or 5pm on Thursday?

Sorry, crazy schedule this week.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b6 Mobile: b6

From: Culp, Michelle (NIH/OD) [E] < b6 >
Sent: Wednesday, May 20, 2020 3:26 PM
To: Santos, Michael (FNIH) [T] b6 ; Tountas, Karen (FNIH) [T] < b6 >
Adam, Stacey (FNIH) [T] b6
Cc: Tolman, Brett < b6 >
Subject: RE: ACTIV Introduction

Good idea. I'm available Thursday from 3:00-4:30 and Friday is wide open.
-Michelle

From: Santos, Michael (FNIH) [T] b6
Sent: Wednesday, May 20, 2020 3:23 PM
To: Tountas, Karen (FNIH) [T] b6 ; Adam, Stacey (FNIH) [T] b6 ; Culp, Michelle (NIH/OD) [E] < b6 >
Cc: Tolman, Brett < b6 >
Subject: RE: ACTIV Introduction

I'd be happy to meet together.

As an FYI to Karen and Stacey, Brett and I set up a meeting with Michelle and Ellen tomorrow at 8am to go over an intro to what's happening in Vaccines and where we're headed. I'm guessing logistically this meeting will end up happening after that one, which would be ideal for our sequencing.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science & Foundation for the National Institutes of Health

From: Tountas, Karen (FNIH) [T] b6
Sent: Wednesday, May 20, 2020 3:00 PM
To: Adam, Stacey (FNIH) [T] <b6>; Culp, Michelle (NIH/OD) [E] b6
Santos, Michael (FNIH) [T] <b6>
Subject: RE: ACTIV Introduction

All –

It might be most efficient to meet all together, especially since there will be increased interactions between the working group that I facilitate and the others.

My 2 cents worth...

Karen

From: Adam, Stacey (FNIH) [T] <b6>
Sent: Wednesday, May 20, 2020 2:28 PM
To: Culp, Michelle (NIH/OD) [E] b6 >; Santos, Michael (FNIH) [T]
b6 >; Tountas, Karen (FNIH) [T] b6
Subject: RE: ACTIV Introduction

Hi Michelle,

I would be happy to meet to go over what is going on in my WG. I am happy to try and find a time for the group on our calendars if Mike and Karen would like.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 Mobile:b6

From: Culp, Michelle (NIH/OD) [E] b6 >
Sent: Wednesday, May 20, 2020 10:48 AM
To: Adam, Stacey (FNIH) [T] b6 >; Santos, Michael (FNIH) [T] b6 >;
Tountas, Karen (FNIH) [T] b6
Subject: ACTIV Introduction

Dear Stacey, Mike and Karen,
It was nice meeting you this morning on WebEx. I'm ready to get started and help where needed. I'll listen to the ACTIV Exec Comm meeting this afternoon to learn more about status of activities.

I'd like to have a brief call with for you to learn how I can help advise, influence or wrangle to move things ahead. It sounds like your calendars are busy. My calendar is still relatively open and flexible. If you think a call would be helpful, please feel free to suggest a time or just go ahead and add a time to my calendar.

All the best,
Michelle

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDECS66C26C2A-GADBOISEL]
Sent: 5/20/2020 9:34:26 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: All of Us program and vaccine trials?

Got it—just let me know if you need me to do something.

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Wednesday, May 20, 2020 5:32 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Cc: Tountas, Karen (FNIH) [T] <[REDACTED]>
Subject: FW: All of Us program and vaccine trials?

Ellen, here is a bit of correspondence on the All of Us stuff. Karen can bring you up to speed and tell you whether further help is needed.

From: Tountas, Karen (FNIH) [T] <[REDACTED]>
Sent: Monday, May 18, 2020 6:14 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Denny, Joshua (NIH/OD) [E] <[REDACTED]>
Cc: Wholley, David (FNIH) [T] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>
Subject: RE: All of Us program and vaccine trials?

Dear Francis,

Your email is very timely. The Clinical Trial Capacity Working Group (CTC WG) had very briefly brought up the ALL of Us program very early in their discussions, but had, at that time, focused intently on generating a CRO/SMO/Network/ Site inventory for therapeutics. And, now, vaccines trials are on the horizon so...

Josh - It would be very interesting to the CTC WG members to hear about the program and to explore with you how ACCTV might harness its potential for vaccine trials. Would you have time to talk with the WG? We meet on Tuesdays and Fridays at 9 am via Zoom. Would this Friday, May 22, or next Tuesday, May 26, work for you? Many thanks for considering this opportunity.

Cheers!
Karen

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Monday, May 18, 2020 5:59 PM
To: Wholley, David (FNIH) [T] <[REDACTED]>; Tountas, Karen (FNIH) [T] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>
Cc: Denny, Joshua (NIH/OD) [E] <[REDACTED]>
Subject: All of Us program and vaccine trials?

Hi David, Karen, and Stacey,

A couple of weeks ago I brought up the idea of exploring the possibility of enlisting the *All of Us* program as a source of volunteers for COVID-19 vaccine trials. With ~240,000 motivated and highly diverse participants, pre-consented for recontact, and located all over the country including areas where COVID-19 is actively spreading, this seems like an interesting opportunity. And there are repository biospecimens available for them too.

Did that discussion go anywhere? Josh Denny (cc'd here), the CEO of *All of Us*, would be glad to engage with you about specifics if that would help.

Francis

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 6/5/2020 1:04:34 AM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0fb5e52c31a4-tuckerjm]
Subject: Fwd: Data-Sharing

Sent from my iPhone

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" <[REDACTED] b6>
Date: June 4, 2020 at 5:23:16 PM EDT
To: "Culp, Michelle (NIH/OD) [E]" <[REDACTED] b6> "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED] b6>
Subject: FW: Data-Sharing

Taking the liberty of sending you this. I also emailed my thoughts to Larry.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew <[REDACTED] b6> Paul Stoffel <[REDACTED] b6>
Heatherington, Anne <[REDACTED] b6>
Cc: Mikael Dolsten MD PhD <[REDACTED] b6> Wholley, David (FNIH) [T] <[REDACTED] b6> Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6> Freire, Maria (FNIH) [T] <[REDACTED] b6> Austin, Christopher (NIH/NCATS) [E] <[REDACTED] b6>
Subject: RE: Data-Sharing

Hi Andy,

Thanks for your leadership on these critical data sharing issues -- and yes, a group of us from NIH/FNIH would very much like to meet with you, Anne, and any others that you think would assist the conversation. I have already asked my principal Deputy, Dr. Larry Tabak, to assemble the right NIH group to take part in this conversation, and I will count on David to figure out who should attend from FNIH.

One of the items that I know the group will want to know more about is the Gates Accelerator -- it's been hard to get a sense of the architecture and ease of use. Is there a beta test model available that we could try out?

Best, Francis

-----Original Message-----

From: Plump, Andrew <[REDACTED] b6>
Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6> Paul Stoffel <[REDACTED] b6>
Heatherington, Anne <[REDACTED] b6>

Cc: Mikael Dolsten MD PhD <

b6

Wholley, David (FNIH) [T]

< b6

Subject: Data-Sharing

Hi Francis and Paul,

Terrific ACTIV leadership meeting yesterday. Remarkable progress.

Following up on the HEVER dialogue on data-sharing. I know you are fully on board with the need for essentially real-time data sharing of emerging clinical trial data, and there is a team that has identified a framework that should work for the NIH. While there may be arcane US government provisions to which we are not aware, the privacy considerations are at least as stringent within industry, and essentially all companies have agreed to the framework Anne presented, so I do not imagine roadblocks.

My suggestion is that Anne and members of the data-sharing group meet with you, David, and/or whomever else you would suggestion from NIH/ACTIV to bring you up to speed and figure out a path forward.

Thanks,
Andy

Sent from my iPad

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 5/13/2020 6:20:39 PM
To: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
CC: Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Sbbac95b1f6e4514a299b318030c31f6-shawcy]
Subject: RE: Meet to discuss new liaison roles

Hi Dina,
I'm free at all of those times.
Thanks,
Ellen

From: Simon, Dina (NIH/OD) [C] <[REDACTED]>
Sent: Wednesday, May 13, 2020 2:18 PM
To: Wholley, David (FNIH) [T] <[REDACTED]>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> Burrus-Shaw, Cyndi (NIH/OD) [E] <[REDACTED]> Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>
Subject: Re: Meet to discuss new liaison roles

Good afternoon,

In continuation of Dr. Tabak's email, his current availability to meet is as follows:

Friday, May 15th 9:15 – 9:45 AM
Monday, May 18th 1:30 – 2:00 PM
Wednesday, May 20th 10:00 – 10:30 AM

Please advise which day would work best for you.

Thanks,
Dina

From: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]>
Date: Wednesday, May 13, 2020 at 1:30 PM
To: "Wholley, David (FNIH) [T]" <[REDACTED]>
Cc: "Culp, Michelle (NIH/OD) [E]" <[REDACTED]> "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> "Burrus-Shaw, Cyndi (NIH/OD) [E]" <[REDACTED]> "Simon, Dina (NIH/OD) [C]" <[REDACTED]>
Subject: Meet to discuss new liaison roles

David,

As you discussed with Francis, Michelle Culp and Ellen Gadbois stand ready to assist with enhancing communications/actions between NIH and FNIH for the ACTIV program. Francis, Carne, and I have discussed, and for the purpose of this activity Michelle and Ellen will use me as their point of contact at NIH.

I would appreciate holding an initial meeting for the three of us with you and any other members of your team you wish to include to scope out initial activities etc. A member of my team will reach out to set up a time.

Best wishes,
Larry

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 3/4/2021 6:39:04 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: I'm confused

Hi Ellen,

The starting of the this current activity was approved by ACTIV trial leadership and the war room group both.

As for best to chat at 6pm, we can do via phone unless Michelle wants to join and if so I will sent up a webex.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 | Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] <b6>
Sent: Thursday, March 4, 2021 1:12 PM
To: Adam, Stacey (FNIH) [T] <b6>
Cc: Culp, Michelle (NIH/OD) [E] <b6>
Subject: RE: I'm confused

Thanks. I think 6 p.m. works tonight for me. Let me know what's the easiest way to do it.

One Q for now—who is "leadership"? NIH war room folks?

From: Adam, Stacey (FNIH) [T] b6
Sent: Thursday, March 4, 2021 12:51 PM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: RE: I'm confused

Thanks, Ellen,

All of your points are well taken and we should likely find some more time to discuss. I am in meetings all day, but could talk post 6pm tonight again.

As to your first question, we were asked to start the activities of today by the leadership assuming that we would just be setting priorities and criteria. The group strayed dramatically, and I admit I was not expecting that and therefore not fully prepared to get us back on the rails.

As for what we would be sending out via email for feedback, we can limit a bit and just focus on priorities and feedback for now and not touch funding and process until you have a chance to speak with LT.

GADB0000001314

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: **b6** | Mobile: **b6**

From: Gadbois, Ellen (NIH/OD) [E] **b6**

Sent: Thursday, March 4, 2021 12:21 PM

To: Adam, Stacey (FNIH) [T] **b6**

Cc: Culp, Michelle (NIH/OD)

Subject: RE: I'm confused

Hi Stacey,

I'm sure you are prepping for your next meeting. I'm available if you want to call me at **b6** I guess here are my questions/thoughts:

- 1) I'm not sure who gave the OK to start this activity—what is your understanding? I know David make a proposal with the review committee, and the oversight committee, but I thought FNIH wasn't interested in running any of it. So I've developed other options that I believe that Dr. Tabak is currently considering. I need to give LT a heads up that much (I'd say all) of the function has been initiated.
- 2) Assuming that things stay as they are.. I think NIH folks need to talk amongst themselves about the implications of any scoring or requirement for funding. It seems to me to be a catch-22 of you need (or will score better if you have) funding for the ACTIV review, but NIH peer reviewers will score applications badly if there isn't a letter of support for the biospecimens or data. Whatever the system is, I think it needs to be totally fair for all NIH applicants.
- 3) Personal opinion is that if this group can just work on priorities (meaning research priorities) and criteria (forget funding), and give that framework as advice to the trial leads, that seems fair/simple. I think that leaves NIH ICs room to get involved later with the trial leads. But I have not talked to anyone else about that.

Anyway, you could use Libby Higgs's point that ACTIV leadership should weigh in on this and maybe you can hit the pause button on an email that looks like putting something to a vote until we give Dr. Tabak an opportunity to comment.
Ellen

From: Adam, Stacey (FNIH) [T] < **b6**

Sent: Thursday, March 4, 2021 11:48 AM

To: Gadbois, Ellen (NIH/OD) [E] **b6**

Cc: Culp, Michelle (NIH/OD) [E]

Subject: RE: I'm confused

Hi Ellen,

Priorities and criteria was the intention. This has taken a turn.
Keep in mind these are the trial leads, so they are likely thinking more tactically.

We can chat after.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships

Direct: b6 | Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] < b6

Sent: Thursday, March 4, 2021 11:46 AM

To: Adam, Stacey (FNIH) [T] b6

Cc: Culp, Michelle (NIH/OD)

Subject: I'm confused

I thought this group wasn't going to set up concrete decisions of who gets biospecimens. Did they ever just discuss developing criteria & priorities (maybe the same thing) and just giving that as advice to the trial leads for their consideration? Then let the trial leads decide how to implement?

Happy to talk after but felt like I should speak up now to you.

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy

Office of Science Policy

Office of the Director

National Institutes of Health

Building 1 Suite 218

voice: b6

fax: 301-402-0280



National Institutes of Health
Turning Discovery into Health

From: Letts, Kinshasa (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E77DE83D1D74A83A70DB2561226CF9C-LETTSKL]
Sent: 3/3/2021 6:32:38 PM
Subject: RE: conversation on 2 policy issues in ACTIV

Good Afternoon,

A calendar invite has been generated for tomorrow, March 4 @ 9am.

Warm regards,

- Kinshasa

From: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, March 3, 2021 1:25 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**; Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**; Letts, Kinshasa (NIH/OD) [C] <[REDACTED]> **b6**
Subject: RE: conversation on 2 policy issues in ACTIV

Ellen and Joe,

Sure, happy to discuss. Kinshasa, can you please work to find a time where all listed here are available?

Thanks,

Jessica

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, March 3, 2021 1:15 PM
To: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6** >
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6** >; Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**; Letts, Kinshasa (NIH/OD) [C] <[REDACTED]> **b6** >
Subject: conversation on 2 policy issues in ACTIV

Hi Jessica,

I was just on a call with the FNIH folks working on ACTIV and Joe Menetski (cc'd here) noted that there are 2 recurring topics in the ACTIV preclinical working group that are NIH policy issues. Joe would like to find a way to move them out of the ongoing ACTIV conversations. I thought the best next step is for you and Joe to talk—I'm happy to be on and am copying Michelle in case she can join. As we've all talked about before, there are things related to the emerging variants. Second, there is also discussion about moving animals from BSL3 to BLS2.

Hopefully Kinshasa can help us find some time together.

Ellen

*Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218*

voice: b6
fax: 301-402-0280



National Institutes of Health
Turning Discovery into Health

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 3/3/2021 6:27:06 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Letts, Kinshasa (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e77de83d1d74a83a70db2561226cf9c-lettskl]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: conversation on 2 policy issues in ACTIV

Thank you so much. Cheryl, can you help with my calendar?

Best,
Joe

From: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, March 3, 2021 1:25 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**; Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**; Letts, Kinshasa (NIH/OD) [C] <[REDACTED]> **b6**
Subject: RE: conversation on 2 policy issues in ACTIV

Ellen and Joe,

Sure, happy to discuss. Kinshasa, can you please work to find a time where all listed here are available?

Thanks,

Jessica

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, March 3, 2021 1:15 PM
To: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**; Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**; Letts, Kinshasa (NIH/OD) [C] <[REDACTED]> **b6**
Subject: conversation on 2 policy issues in ACTIV

Hi Jessica,

I was just on a call with the FNIH folks working on ACTIV and Joe Menetski (cc'd here) noted that there are 2 recurring topics in the ACTIV preclinical working group that are NIH policy issues. Joe would like to find a way to move them out of the ongoing ACTIV conversations. I thought the best next step is for you and Joe to talk—I'm happy to be on and am copying Michelle in case she can join. As we've all talked about before, there are things related to the emerging variants. Second, there is also discussion about moving animals from BSL3 to BLS2.

Hopefully Kinshasa can help us find some time together.

Ellen

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280



National Institutes of Health
Turning Discovery into Health

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 12/30/2020 3:24:25 PM
To: Lohmann, Larry (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f4206cbb2c4d82adbc1eda15e035c4-lohmannll]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Everett, Chris (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10f3011a5ef4472594cc0aef86875864-everettcl]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: questions from Chairman Johnson for FC on ACTIV

Dear Larry and Chris,

I reviewed the NCATS letter and think it's thorough. As OLPA reviews the incoming information from ICs for consistency, I might suggest the examples of specific products (pg 2-3) provided in the NCATS letter not be included.

With regard to ivermectin, I understand from Stacey Adams (FNIH) that NIAID is completing pre-clinical testing on inhaled and oral ivermectin. If results are positive, ivermectin would be reassessed. NCATS' summary indicates ivermectin "was also shown to be toxic to human cells at those same concentrations, which may detract from its possible utility." The 2 statements might be potentially inconsistent.

Best,
Michelle

From: Lohmann, Larry (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, December 30, 2020 6:27 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6 Brodd, Lauren (NIH/OD) [E] <[REDACTED]> b6 Everett, Chris (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: questions from Chairman Johnson for FC on ACTIV

Good morning,

Today it is my turn to disappear for a few days. Attached is the contribution from NCATS, just for reference. Please note Chris Everett is cc'd here and will be the POC for this issue in OLPA while I am out. We are still waiting on NIAID. I spoke to Chase Crawford yesterday, that may come as soon as today.

Very respectfully,
Larry

From: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> b6
Date: Saturday, December 26, 2020 at 9:08 PM
To: "Lohmann, Larry (NIH/OD) [E]" <[REDACTED]> b6
Cc: "Culp, Michelle (NIH/OD) [E]" <[REDACTED]> b6 >, "Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> b6
Subject: FW: questions from Chairman Johnson for FC on ACTIV

Hi Larry,

Tomorrow morning I am heading to a cabin with no cell signal. I'll be back in town Wednesday Dec 30 and still on leave, so I will just check email a few times. I think David gave reasonable answers to questions

1 and 3 below. I would just of course take out the sentence about listing every drug—I think it would be fair to wait and see if Senator Johnson really wants more details on the repurposed drugs (beyond ivermectin, and I don't know the story there).

So far I've only seen a response to Q2 back from NHLBI, which I forwarded to you. I put Michelle Culp on my out of office message (sorry Michelle) so hopefully if NIAID and NCATS don't respond to you directly, Michelle could forward them.

Hope this works out without too much fuss.

Elen

1) What repurposed drugs have been investigated?

ACTIV has reviewed over 500 different potential drugs for COVID-19. We have approached this from the standpoint of what are the most promising drugs?, regardless of whether or not they are repurposed or novel per se. However, of course there are many more existing drugs for other indications out there that can be repurposed than there are novel drugs in development, so the preponderance of what we've looked at is in the repurposed category—80% would not be an unreasonable estimate. ~~If the Senator really wants a list of every drug that was considered separated out by repurposed vs. novel I suppose we could do that, but it would take some time.~~ Of the drugs listed on slide 8 in the deck we sent to Ashley, all of the drugs are repurposed except the neutralizing antibodies mentioned in connection with ACTIV-2 and ACTIV-3.

2) ~~How much money has been spent studying existing drugs?~~

~~This is a question for NIH of course.~~

3) Who/what is the group that has been reviewing them?

The ACTIV Agent Prioritization team consists of about 40 experts in the field with knowledge of and broad experience in both basic science and drug development. About 50% are from various federal agencies, 25% from academic research institution, and 25% from industry. They are broken down into three subteams with specific expertise in antivirals, immune modulators, and symptomatic/supportive drugs (such as anticoagulants). The evaluations performed by the subteam are further reviewed with the entire Agent Prioritization team before being forwarded to the trial teams at the NIH. NIH, as the sponsor of the ACTIV trials, makes the final decision regarding which get tested.

From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, December 23, 2020 11:31 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Adam, Stacey (FNIH) [T] b6 >; Menetski, Joseph (FNIH) [T] b6 >; Gonzalez, Nina b6 >; Chen, Helen b6 >
Cc: Parker, Ashley (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6 Brodd, Lauren (NIH/OD) [E] < b6 Lohmann, Larry (NIH/OD) [E] b6 , Freire, Marla (FNIH) [T] b6 Appell, Evan b6
Subject: RE: questions from Chairman Johnson for FC on ACTIV
Importance: High

Please see answers in italics below. I hope this is sufficiently comprehensive.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, December 23, 2020 10:37 AM
To: Wholley, David (FNIH) [T] b6 Adam, Stacey (FNIH) [T] b6 >; Menetski, Joseph (FNIH) [T] b6 Gonzalez, Nina b6 ; Chen, Helen < b6
Cc: Parker, Ashley (NIH/OD) [E] < b6 ; Culp, Michelle (NIH/OD) [E] b6 Brodd,

Subject: questions from Chairman Johnson for FC on ACTIV

Dear FNIH and Deloitte folks,

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For question #2...I don't expect that you have that information, but if you have any thoughts on who I should check with to come up with some kind of answer, I'd appreciate it.

I'm copying Larry Lohmann, a colleague in NIH's leg affairs shop, to expedite getting a response together.

Thanks very much.

Ellen

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy

Office of Science Policy

Office of the Director

National Institutes of Health

Building 1 Suite 218

voice: b6

fax: 301-402-0280



National Institutes of Health
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From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E2283685FF4E9988E3770CFC7EE770-TABAKL]
Sent: 12/23/2020 5:52:00 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Tucker Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0ffb5e52c31a4-tuckerjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: FYI my plan on developing responses to Sen. Johnson re. ACTIV repurposed drugs

Thanks Ellen; seems like a good approach. Holler if I can help.
Best wishes for healthy and happy Holiday.
Larry

From: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]>
Date: Wednesday, December 23, 2020 at 12:04 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]>
Cc: "Culp, Michelle (NIH/OD) [E]" <[REDACTED]> "Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> "Tucker, Jessica (NIH/OD) [E]" <[REDACTED]> "Parker, Ashley (NIH/OD) [E]" <[REDACTED]>
Subject: FYI my plan on developing responses to Sen. Johnson re. ACTIV repurposed drugs

Dear Larry,

I'm writing to describe my plan to develop a response to Senator Johnson, who sent follow-up questions after Dr. Collins spoke to him yesterday. Sen. Johnson had 3 questions, specifically about repurposed drugs. David Wholley gave his reaction to all 3 (see below). I think I can rework his answers to Q1 and 3. The big hole is Q2: "How much money has been spent studying existing drugs?" I doubt that we can come up with a solid comprehensive answer without major effort, so I am planning on emailing Amy Patterson, Cliff Lane, and Chris Austin (I'll cc you) on whether they have thoughts on what we could say. Perhaps something about how about it would take a substantial portfolio analysis to answer that question, but for example, major NIH-funded research activities include [give some examples]. OLPA thinks we need to respond to Sen. Johnson by Mon/Tues next week, which might be hard even with a few examples since so many staff will be on leave. But I'll see what I can get.

Also just wanted you to know that Maria Freire sent a frustrated reaction (attached) in reaction to this query and a separate one this morning. I tried to express my thanks in the chain below.

Happy Holidays!

Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, December 23, 2020 11:42 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED]> Menetski, Joseph (FNIH) [T] <[REDACTED]> Gonzalez, Nina <[REDACTED]> Chen, Helen <[REDACTED]>

Freire, Maria (FNIH) [T] < b6 Appell, Evan < b6
Cc: Parker, Ashley (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6 Brodd,
Lauren (NIH/OD) [E] < b6 Lohmann, Larry (NIH/OD) [E] < b6
Subject: RE: questions from Chairman Johnson for FC on ACTIV

Thanks very much David and the amazing group at FNIH and Deloitte. I think this is enough for me to work with on the response to Senator Johnson, and Michelle confirmed to me that she has what she needs to deal with the separate question from NIH's Executive Secretariat on a template response about ivermectin questions. So hopefully that's it on these two requests.

I hope that you all are able to step away and enjoy holiday activities. I am in awe of how you manage this massive enterprise with such high professionalism and energy.

Best,
Ellen

From: Wholley, David (FNIH) [T] < b6
Sent: Wednesday, December 23, 2020 11:31 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6 >; Adam, Stacey (FNIH) [T] < b6 Menetski, Joseph (FNIH) [T] < b6 >; Gonzalez, Nina < b6 >; Chen, Helen < b6 >
Cc: Parker, Ashley (NIH/OD) [E] < b6 >; Culp, Michelle (NIH/OD) [E] < b6 >; Brodd, Lauren (NIH/OD) [E] < b6 >; Lohmann, Larry (NIH/OD) [E] < b6 >; Freire, Maria (FNIH) [T] < b6 >; Appell, Evan < b6 >
Subject: RE: questions from Chairman Johnson for FC on ACTIV
Importance: High

Please see answers in italics below. I hope this is sufficiently comprehensive.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, December 23, 2020 10:37 AM
To: Wholley, David (FNIH) [T] < b6 >; Adam, Stacey (FNIH) [T] < b6 >; Menetski, Joseph (FNIH) [T] < b6 >; Gonzalez, Nina < b6 >; Chen, Helen < b6 >
Cc: Parker, Ashley (NIH/OD) [E] < b6 >; Culp, Michelle (NIH/OD) [E] < b6 >; Brodd, Lauren (NIH/OD) [E] < b6 >; Lohmann, Larry (NIH/OD) [E] < b6 >
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an unreasonable estimate. If the Senator really wants a list of every drug that was considered separated out by repurposed vs. novel I suppose we could do that, but it would take some time. Of the drugs listed on slide 8 in the deck we sent to Ashley, all of the drugs are repurposed except the neutralizing antibodies mentioned in connection with ACTIV-2 and ACTIV-3.

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I'm copying Larry Lohmann, a colleague in NIH's leg affairs shop, to expedite getting a response together.

Thanks very much.

Ellen

Ellen L. Gadbois, Ph.D.

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voice: b6

fax: 301-402-0280



From: Lohmann, Larry (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93F4206CBB2C4D82ADBC1EDA15E035C4-LOHMANNLL]
Sent: 12/23/2020 4:20:44 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: Re: questions from Chairman Johnson for FC on ACTIV

Understandable. I asked Adrienne and she said like "Monday-Tuesday." Hopefully, that is helpful.

Sorry,
Larry

From: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Wednesday, December 23, 2020 at 11:15 AM
To: "Lohmann, Larry (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: questions from Chairman Johnson for FC on ACTIV

Thanks, Larry. How far into next week do you think is reasonable? I think Q1 may take some work. They have looked at hundreds of compounds and I don't know how hard it will be to find the repurposed ones.

From: Lohmann, Larry (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, December 23, 2020 11:14 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: questions from Chairman Johnson for FC on ACTIV

Hey Ellen,

I think getting it back next week would be fine. I just wanted to make sure the iron was in the fire, so to speak.

Very respectfully,
Larry

From: "Freire, Maria (FNIH) [T]" <[REDACTED]> **b6**
Date: Wednesday, December 23, 2020 at 11:11 AM
To: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> **b6** >, "Wholley, David (FNIH) [T]" <[REDACTED]> **b6** >,
"Adam, Stacey (FNIH) [T]" <[REDACTED]> **b6** "Menetski, Joseph (FNIH) [T]" <[REDACTED]> **b6** "Gonzalez,
Nina" <[REDACTED]> **b6** "Chen, Helen" <[REDACTED]> **b6** >
Cc: "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6** >, "Culp, Michelle (NIH/OD) [E]" <[REDACTED]> **b6**
"Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> **b6** "Lohmann, Larry (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: questions from Chairman Johnson for FC on ACTIV

You'll forgive my frustration, which comes after many, many months of non-stop dedication from our folks but good heavens, this is really make-work! Nothing for it, I suppose but is there any way to bring those disparate requests together and limit their scope so folks don't have to spend Christmas Eve and Christmas day working? M.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, December 23, 2020 11:03 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6** ; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** >; Menetski, Joseph

(FNIH) [T] b6 Gonzalez, Nina < b6 ; Chen, Helen b6 >
Cc: Parker, Ashley (NIH/OD) [E] < b6 >; Culp, Michelle (NIH/OD) [E] < b6 Brodd,
Lauren (NIH/OD) [E] b6 Lohmann, Larry (NIH/OD) [E] b6 >; Freire, Maria
(FNIH) [T] < b6
Subject: RE: questions from Chairman Johnson for FC on ACTIV

Thanks, David. My request with the questions from Chairman Johnson is separate from Michelle's question about a template NIH response to questions about ivermectin. (I realize that ivermectin in the repurposing category and maybe that's part of the impetus for the Johnson request, but I don't know.)

FYI Larry just told me that the ACTIV slides Ashley prepared may not have been shared with Mr. Johnson, but even if they weren't, they don't specifically break out repurposed drugs.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, December 23, 2020 10:48 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Adam, Stacey (FNIH) [T] < b6 Menetski, Joseph (FNIH) [T] b6 >; Gonzalez, Nina < b6 >; Chen, Helen b6
Cc: Parker, Ashley (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6 >; Brodd, Lauren (NIH/OD) [E] b6 ; Lohmann, Larry (NIH/OD) [E] b >; Freire, Maria (FNIH) [T] < b6
Subject: RE: questions from Chairman Johnson for FC on ACTIV

I'm happy to help, but to whom am I responding? I have emails from both you Ellen and from Michelle, asking slightly different questions.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Wednesday, December 23, 2020 10:37 AM
To: Wholley, David (FNIH) [T] < b6 Adam, Stacey (FNIH) [T] < b6 Menetski, Joseph (FNIH) [T] < b6 >; Gonzalez, Nina b6 Chen, Helen b6
Cc: Parker, Ashley (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] b6 >; Brodd, Lauren (NIH/OD) [E] < b6 Lohmann, Larry (NIH/OD) [E] < b6
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fax: 301-402-0280



National Institutes of Health

Turning Discovery Into Health

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 12/23/2020 4:01:42 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Lohmann, Larry (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f4206cb2c4d82adbc1eda15e035c4-lohmannll]
Subject: RE: questions from Chairman Johnson for FC on ACTIV

OK, answers coming from me momentarily

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, December 23, 2020 10:37 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6** Adam, Stacey (FNIH) [T] <[REDACTED]> **b6** Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6** Gonzalez, Nina <[REDACTED]> **b6** Chen, Helen <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** Brodd, Lauren (NIH/OD) [E] <[REDACTED]> **b6** Lohmann, Larry (NIH/OD) [E] <[REDACTED]> **b6**
Subject: questions from Chairman Johnson for FC on ACTIV

Dear FNIH and Deloitte folks,

I am really sorry to be asking this as I know Stacey is on well-deserved leave and I'm sure others are trying to wrap up work. But.. Dr. Collins spoke to Chairman Ron Johnson yesterday and the Chairman had follow-up questions, specifically regarding repurposed drugs. The Chairman already has the attached slide set, which Ashley provided. (Slides 5-7 focus on the number and category of agents submitted/reviewed by ACTIV to date, but it doesn't break out repurposed drugs.)

With regards to repurposing drugs only for ACTIV:

- 1) What repurposed drugs have been investigated?
- 2) How much money has been spent studying existing drugs?
- 3) Who/what is the group that has been reviewing them?

I'm hoping you can answer question #1 and #3. (For #3, I'm just not sure what is the formal name of the agent prioritization groups and how you describe them.)

For question #2...I don't expect that you have that information, but if you have any thoughts on who I should check with to come up with some kind of answer, I'd appreciate it.

I'm copying Larry Lohmann, a colleague in NIH's leg affairs shop, to expedite getting a response together.

Thanks very much.
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: **b6**
fax: 301-402-0280



National Institutes of Health
Turning Discovery Into Health

From: Lohmann, Larry (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93F4206CBB2C4D82ADBC1EDA15E035C4-LOHMANNLL]
Sent: 12/23/2020 3:59:19 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: Re: questions from Chairman Johnson for FC on ACTIV

I know, I appreciate it. It is a tough time of year to try to track folks down. Thank you so much.

Very respectfully,
Larry

From: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Wednesday, December 23, 2020 at 10:57 AM
To: "Lohmann, Larry (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: questions from Chairman Johnson for FC on ACTIV

Thanks—I'll let the group know. And we are going to need to contact ICs for some sort of estimate on question #2, but I'm not even sure where to start so hoping FNIH will have ideas.

From: Lohmann, Larry (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, December 23, 2020 10:48 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: questions from Chairman Johnson for FC on ACTIV

Dr. Gadbois,

Just wanted to clarify the slide deck was prepared for Dr. Collins. I do not believe Chairman Johnson has seen it.

Very respectfully,
Larry

From: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Wednesday, December 23, 2020 at 10:39 AM
To: "Wholley, David (FNIH) [T]" <[REDACTED]> **b6**, "Adam, Stacey (FNIH) [T]" <[REDACTED]> **b6**, "Menetski, Joseph (FNIH) [T]" <[REDACTED]> **b6**, "Gonzalez, Nina" <[REDACTED]> **b6**, "Chen, Helen" <[REDACTED]> **b6**
Cc: "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6**, "Culp, Michelle (NIH/OD) [E]" <[REDACTED]> **b6**, "Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> **b6**, "Lohmann, Larry (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: questions from Chairman Johnson for FC on ACTIV

Dear FNIH and Deloitte folks,

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- 1) What repurposed drugs have been investigated?
- 2) How much money has been spent studying existing drugs?
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I'm copying Larry Lohmann, a colleague in NIH's leg affairs shop, to expedite getting a response together.

Thanks very much.
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: [REDACTED] b6
fax: 301-402-0280



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/21/2020 10:00:14 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Ivermectin

Thanks, Ashley!

You too!

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 Mobile: b6

From: Parker, Ashley (NIH/OD) [E] <b6>
Sent: Monday, December 21, 2020 4:48 PM
To: Adam, Stacey (FNIH) [T] <b6>
Cc: Wholley, David (FNIH) [T] <b6> Gadbois, Ellen (NIH/OD) [E] <b6> Brodd, Lauren (NIH/OD) [E] <b6>
Subject: RE: Ivermectin

Hi Stacey,

We will insert the language provided below – It's not too long.

Happy holidays and I hope you enjoy a much deserved vacation! 🍷

Thank you,
Ashley

From: Adam, Stacey (FNIH) [T] b6
Sent: Monday, December 21, 2020 4:44 PM
To: Parker, Ashley (NIH/OD) [E] <b6>
Cc: Wholley, David (FNIH) [T] <b6> Gadbois, Ellen (NIH/OD) [E] <b6> Brodd, Lauren (NIH/OD) [E] <b6>
Subject: RE: Ivermectin

Hi Ashley,

The team will be sending ivermectin to the immune modulator team to review in January.

However, I think it might be better to say that ACTIV team has chosen not to move forward with ivermectin based on currently evaluated data, but the team will be tracking any forthcoming information and will re-evaluate if new information becomes available.

If this is too long, I guess you can leave what you have, but it will cause you to get another letter I would imagine in about a week to find out if the review is done.

On the other note, I also will be on leave after tomorrow, so hopefully, I won't need to trouble Ellen or Lauren.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: b6 Mobile: (b6

From: Parker, Ashley (NIH/OD) [E] b6 >
Sent: Monday, December 21, 2020 4:34 PM
To: Adam, Stacey (FNIH) [T] b6
Cc: Wholley, David (FNIH) [T] b6 ; Gadbois, Ellen (NIH/OD) [E] b6 Brodd, Lauren (NIH/OD) [E] < b6
Subject: RE: Ivermectin

Hi Stacey,

Our ES prepared the attached response to several incoming inquiries about the evaluation of Ivermectin. This draft was based on prior email exchange but I remember hearing the decision was made to not move forward but possibly re-evaluate the compound with a different team.

I wanted to confirm, do we want to convey the decision was made to not move forward with Ivermectin at this time or share the ACTIV team is currently in the process of reevaluating ivermectin based on new data?

FYI — will be on leave starting tomorrow and returning on Jan. 7th in case you receive any inquiries between now and then from Ellen G. or Lauren Brodd in OD.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, December 16, 2020 8:22 AM
To: Collins, Francis (NIH/OD) [E] b6 >; Adam, Stacey (FNIH) [T] < b6 Parker, Ashley (NIH/OD) [E] b6 >
Cc: Hallett, Adrienne (NIH/OD) [E] < b6 Freire, Maria (FNIH) [T] b6 >
Subject: RE: Ivermectin

Ivermectin is being reviewed by the Agent Prioritization Antiviral Subteam at about 4pm this afternoon.

From: Collins, Francis (NIH/OD) [E] b6
Sent: Wednesday, December 16, 2020 6:54 AM
To: Wholley, David (FNIH) [T] b6 Adam, Stacey (FNIH) [T] b6 Parker, Ashley

(NIH/OD) [E]

b6

Cc: Hallett, Adrienne (NIH/OD) [E]

b6

Subject: Ivermectin

Anything new in the prioritization re-review of ivermectin? Getting some pressure from a couple of Senators....

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/23/2020 3:30:46 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: TIME SENSITIVE RESPONSE: ivermectin

Hi Michelle,

Yes, we are tracking further information emerging that ivermectin may actually be an immune modulator and not an antiviral. The data is early, but may emerge. Also, Ann Eakin's team at NIAID is running some preclinical testing on both inhaled and oral ivermectin and if that independent testing showed positive results, we would also reassess the committee's decision.

Thanks,
stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 Mobile: b6

From: Culp, Michelle (NIH/OD) [E] < b6 >
Sent: Wednesday, December 23, 2020 10:28 AM
To: Adam, Stacey (FNIH) [T] < b6 > Chen, Helen < b6 > Menetski, Joseph (FNIH) [T] < b6 >
Cc: Gadbois, Ellen (NIH/OD) [E] < b6 > Brodd, Lauren (NIH/OD) [E] < b6 > Wholley, David (FNIH) [T] < b6 >
Subject: RE: TIME SENSITIVE RESPONSE: ivermectin

Stacey,

It sounds like the paragraph from ES is accurate and that it is possible this product *could* be reviewed again. It was suggested we offer more information on what was lacking, but that may open a can of worms if we offer any more detail. If this is the template response, I will accept it.

I do not know who made the inquiry or if this is in follow-up to the email that Ellen just flagged.

"The ACTIV team recently completed a reevaluation of ivermectin and, again, has determined that the current data provided for evaluation does not provide strong enough evidence to move forward at this time. The team will continue to track any forthcoming information and will reevaluate if new information becomes available. NIH is committed to

funding the most promising research to advance our ability to treat and prevent COVID-19 with the resources available to us."

From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Wednesday, December 23, 2020 10:20 AM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]>; Chen, Helen <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Brodd, Lauren (NIH/OD) [E] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>
Subject: RE: TIME SENSITIVE RESPONSE: ivermectin

Hi Michelle,

There was no company that submitted Ivermectin this last time. The re-evaluation was done on publicly available data that the team acquired and reviewed at the behest of ACTIV and OWS leadership.

I can send to you the full details that I sent to FC and was provided to Janet. Ashley had used this to boil down the general response. I will forward to you all in another email.

Can you tell me who is asking for more detail to be provided? I know a few of the NIAID team had suggested this, but I was not sure if it was in response to something specific.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] Mobile: [REDACTED]

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, December 23, 2020 9:52 AM
To: Chen, Helen <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Brodd, Lauren (NIH/OD) [E] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>
Subject: TIME SENSITIVE RESPONSE: ivermectin
Importance: High

Dear Joe and Helen,
I'm hoping you can help me this morning/ASAP. I see Stacey is out, so I'm ccing her as FYI.
NIH is responding to an inquiry about ivermectin and its agent prioritization outcome. I need your assistance in reviewing the paragraph below.

"The ACTIV team recently completed a reevaluation of ivermectin and, again, has determined that the current data provided for evaluation does not provide strong enough evidence to move forward at this time. The team will continue to track any forthcoming information and will reevaluate if new information becomes available. NIH is committed to funding the most promising research to advance our ability to treat and prevent COVID-19 with the resources available to us."

It was suggested we add more detail about the reevaluation and why the decision was made. **What detail about the evaluation and decision was provided to the company?** Can you provide any more information, or a "for example...." that would be aligned with the direction of the agent prioritization process?

Many thanks!

-Michelle

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 12/23/2020 3:56:38 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboiset]
Subject: RE: questions from Chairman Johnson for FC on ACTIV

Ellen,
Just to confirm – your request is separate from the ES response and for a different (but similar) request. David should reply to you for those questions.
-M.

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Wednesday, December 23, 2020 10:48 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>; Gonzalez, Nina <[REDACTED]>; Chen, Helen <[REDACTED]>
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Culp, Michelle (NIH/OD) [E] <[REDACTED]>; Brodd, Lauren (NIH/OD) [E] <[REDACTED]>; Lohmann, Larry (NIH/OD) [E] <[REDACTED]>; Freire, Maria (FNIH) [T] <[REDACTED]>
Subject: RE: questions from Chairman Johnson for FC on ACTIV

I'm happy to help, but to whom am I responding? I have emails from both you Ellen and from Michelle, asking slightly different questions

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, December 23, 2020 10:37 AM
To: Wholley, David (FNIH) [T] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Menetski, Joseph (FNIH) [T] <[REDACTED]>; Gonzalez, Nina <[REDACTED]>; Chen, Helen <[REDACTED]>
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Culp, Michelle (NIH/OD) [E] <[REDACTED]>; Brodd, Lauren (NIH/OD) [E] <[REDACTED]>; Lohmann, Larry (NIH/OD) [E] <[REDACTED]>
Subject: questions from Chairman Johnson for FC on ACTIV

Dear FNIH and Deloitte folks,

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- 1) What repurposed drugs have been investigated?
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Thanks very much.

Ellen

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy

Office of Science Policy

Office of the Director

National Institutes of Health

Building 1 Suite 218

voice: b6

fax: 301-402-0280



National Institutes of Health
Turning Discovery Into Health

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/23/2020 3:02:56 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: TIME SENSITIVE RESPONSE: ivermectin

Hi Michelle,

Ashley Parker drafted some language for the ivermectin responses. I will get to my computer and send to you

Stacey

Sent from my iPhone. Please excuse the brevity and typos.

On Dec 23, 2020, at 9:51 AM, Culp, Michelle (NIH/OD) [E] <[REDACTED]> wrote:

Dear Joe and Helen,
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Many thanks!
Michelle

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 12/23/2020 2:59:49 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=User3c2f486d]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: TIME SENSITIVE RESPONSE: ivermectin

Dear Nina,
I should have cc'd you, too. I received an out of office from Helen. Stacey is out, and I don't know if Joe is available. Is there anyone on the Deloitte team who can help answer the question below?
Thanks!

Best regards,
Michelle

From: Culp, Michelle (NIH/OD) [E]
Sent: Wednesday, December 23, 2020 9:52 AM
To: Chen, Helen <[REDACTED]> b6 Menetski, Joseph (FNIH) [T] <[REDACTED]> b6
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6 Brodd, Lauren (NIH/OD) [E] <[REDACTED]> b6 Stacey (FNIH) Adam [T] <[REDACTED]> b6 <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: TIME SENSITIVE RESPONSE: ivermectin
Importance: High

Dear Joe and Helen,
I'm hoping you can help me this morning/ASAP. I see Stacey is out, so I'm ccing her as FYI.
NIH is responding to an inquiry about ivermectin and its agent prioritization outcome. I need your assistance in reviewing the paragraph below.

"The ACTIV team recently completed a reevaluation of ivermectin and, again, has determined that the current data provided for evaluation does not provide strong enough evidence to move forward at this time. The team will continue to track any forthcoming information and will reevaluate if new information becomes available. NIH is committed to funding the most promising research to advance our ability to treat and prevent COVID-19 with the resources available to us."

It was suggested we add more detail about the reevaluation and why the decision was made. **What detail about the evaluation and decision was provided to the company?** Can you provide any more information, or a "for example...." that would be aligned with the direction of the agent prioritization process?

Many thanks!
-Michelle

From: Lohmann, Larry (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93F4206CBB2C4D82ADBC1EDA15E035C4-LOHMANNLL]
Sent: 12/27/2020 2:11:30 AM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: Re: questions from Chairman Johnson for FC on ACTIV

Thanks Ellen,

I'll be out on Wednesday myself for the rest of the week. I'll keep track of them as they're coming in. We will see what else comes back.

Best,
Larry

Sent from my iPhone

On Dec 26, 2020, at 9:08 PM, Gadbois, Ellen (NIH/OD) [E] < b6 wrote:

Hi Larry,

Tomorrow morning I am heading to a cabin with no cell signal. I'll be back in town Wednesday Dec 30 and still on leave, so I will just check email a few times. I think David gave reasonable answers to questions 1 and 3 below. I would just of course take out the sentence about listing every drug—I think it would be fair to wait and see if Senator Johnson really wants more details on the repurposed drugs (beyond ivermectin, and I don't know the story there).

So far I've only seen a response to Q2 back from NHLBI, which I forwarded to you. I put Michelle Culp on my out of office message (sorry Michelle) so hopefully if N AID and NCATS don't respond to you directly, Michelle could forward them.

Hope this works out without too much fuss.

Ellen

1) What repurposed drugs have been investigated?

ACTIV has reviewed over 500 different potential drugs for COVID-19. We have approached this from the standpoint of what are the most promising drugs?, regardless of whether or not they are repurposed or novel per se. However, of course there are many more existing drugs for other indications out there that can be repurposed than there are novel drugs in development, so the preponderance of what we've looked at is in the repurposed category—80% would not be an unreasonable estimate.—If the Senator really wants a list of every drug that was considered separated out by repurposed vs. novel I suppose we

~~could do that, but it would take some time.~~ Of the drugs listed on slide 8 in the deck we sent to Ashley, all of the drugs are repurposed except the neutralizing antibodies mentioned in connection with ACTIV-2 and ACTIV-3.

2) ~~How much money has been spent studying existing drugs?~~

~~This is a question for NIH of course.~~

3) Who/what is the group that has been reviewing them?

The ACTIV Agent Prioritization team consists of about 40 experts in the field with knowledge of and broad experience in both basic science and drug development. About 50% are from various federal agencies, 25% from academic research institution, and 25% from industry. They are broken down into three subteams with specific expertise in antivirals, immune modulators, and symptomatic/supportive drugs (such as anticoagulants). The evaluations performed by the subteam are further reviewed with the entire Agent Prioritization team before being forwarded to the trial teams at the NIH. NIH, as the sponsor of the ACTIV trials, makes the final decision regarding which get tested.

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Wednesday, December 23, 2020 11:31 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED]>
Menetski, Joseph (FNIH) [T] <[REDACTED]> Gonzalez, Nina <[REDACTED]> Chen,
Helen <[REDACTED]>
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> Culp, Michelle (NIH/OD) [E]
<[REDACTED]> Brodd, Lauren (NIH/OD) [E] <[REDACTED]> Lohmann, Larry
(NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Appell, Evan
<[REDACTED]>
Subject: RE: questions from Chairman Johnson for FC on ACTIV
Importance: High

Please see answers in italics below. I hope this is sufficiently comprehensive.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, December 23, 2020 10:37 AM
To: Wholley, David (FNIH) [T] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>
Menetski, Joseph (FNIH) [T] <[REDACTED]>; Gonzalez, Nina <[REDACTED]>; Chen,
Helen <[REDACTED]>
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Culp, Michelle (NIH/OD) [E]
<[REDACTED]> Brodd, Lauren (NIH/OD) [E] <[REDACTED]> Lohmann, Larry
(NIH/OD) [E] <[REDACTED]>
Subject: questions from Chairman Johnson for FC on ACTIV

Dear FNIH and Deloitte folks,

I am really sorry to be asking this as I know Stacey is on well-deserved leave and I'm sure others are trying to wrap up work. But...Dr. Collins spoke to Chairman Ron Johnson yesterday and the Chairman had follow up questions, specifically regarding repurposed drugs. The Chairman already has the attached slide set, which Ashley provided. (Slides 5-7 focus on the number and category of agents submitted/reviewed by ACTIV to date, but it doesn't break out repurposed drugs.)

With regards to repurposing drugs only for ACTIV:

1) What repurposed drugs have been investigated?

ACTIV has reviewed over 500 different potential drugs for COVID-19. We have approached this from the standpoint of what are the most promising drugs?, regardless of whether or not they are repurposed or novel per se. However, of course there are many more existing drugs for other indications out there that can be repurposed than there are novel drugs in development, so the preponderance of what we've looked at is in the repurposed category—80% would not be an unreasonable estimate. If the Senator really wants a list of every drug that was considered separated out by repurposed vs. novel I suppose we could do that, but it would take some time. Of the drugs listed on slide 8 in the deck we sent to Ashley, all of the drugs are repurposed except the neutralizing antibodies mentioned in connection with ACTIV-2 and ACTIV-3.

2) How much money has been spent studying existing drugs?

This is a question for NIH of course.

3) Who/what is the group that has been reviewing them?

The ACTIV Agent Prioritization team consists of about 40 experts in the field with knowledge of and broad experience in both basic science and drug development. About 50% are from various federal agencies, 25% from academic research institution, and 25% from industry. They are broken down into three subteams with specific expertise in antivirals, immune modulators, and symptomatic/supportive drugs (such as anticoagulants). The evaluations performed by the subteam are further reviewed with the entire Agent Prioritization team before being forwarded to the trial teams at the NIH. NIH, as the sponsor of the ACTIV trials, makes the final decision regarding which get tested.

I'm hoping you can answer question #1 and #3 (For #3, I'm just not sure what is the formal name of the agent prioritization groups and how you describe them.)

For question #2...I don't expect that you have that information, but if you have any thoughts on who I should check with to come up with some kind of answer, I'd appreciate it.

I'm copying Larry Lohmann, a colleague in NIH's leg affairs shop, to expedite getting a response together.

Thanks very much.
Ellen

*Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: [REDACTED] b6
fax: 301-402-0280*

<image001.png>

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 12/4/2020 8:59:05 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboise]
Subject: RE: Zeke's comment about ACTIV IRB

I told you as much as I knew. Hope it was enough.

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, December 4, 2020 3:47 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Zeke's comment about ACTIV IRB

David,

I'm interested in understanding where Zeke might have been going about the IRB review. I'm wondering if he thinking it would fall into the public health surveillance exception? OSP would be interested to know what was behind his question, if you know.

Thanks!

-Michelle

Adam, Stacey (FNIH) [T]; Alvarez, Rosa Maria; Margaret Anderson, Appell, Evan; Chen, Helen Q.; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Santos, Michael (FNIH) [T]; Stratton, Benjamin; btolman; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; asorosa; Connelly, Sarah
Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]
Subject: ACTIV EC & WG Co-chair Pre-call
When: Monday, November 2, 2020 4:45 PM-5.15 PM (UTC-05:00) Eastern Time (US & Canada).
Where: see webex be ow

Dr. Collins has a conflict at 4:15 rescheduling to 4:45 p.m.

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Join using Microsoft Lync or Microsoft Skype for Business

Dial **b6** @ync.webex.com

If you are a host, [click here](#) to view host information.

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 10/21/2020 4:04:45 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]
CC: Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]
Subject: RE: Access Instructions: COVID-19 Clinical Trial Tracker
Attachments: COVID-19 Clinical Trial Tracker - Access Instructions.pdf

After the discussion of the tracker from which Janet's EC slides came, I am re-sending this email to remind all that they have access to the browser and all the data, so you can answer the questions you have. Multiple upgrades and improvements have been done since August, and the browser is now quite rich and useful for answering the types of questions raised today.

Let me or Sam Jonson know if you need help or have questions.

Chris

From: Jonson, Samantha (NIH/NCATS) [E] <b6>
Sent: Thursday, August 13, 2020 3:49 PM
To: Collins, Francis (NIH/OD) [E] <b6> Tabak, Lawrence (NIH/OD) [E] <b6> Lane, Cliff (NIH/NIAID) [E] <b6> Freire, Maria (FNIH) [T] <b6> Wholley, David (FNIH) [T] <b6> Menetski, Joseph (FNIH) [T] <b6> Adam, Stacey (FNIH) [T] <b6> Culp, Michelle (NIH/OD) [E] <b6> Gadbois, Ellen (NIH/OD) [E] <b6> Parker, Ashley (NIH/OD) [E] <b6> Gibbons, Gary (NIH/NHLBI) [E] <b6>
Cc: Austin, Christopher (NIH/NCATS) [E] <b6> Kurilla, Michael (NIH/NCATS) [E] <b6> Dickens, Jim (NIH/NCATS) [C] <b6> Cutillo, Christine (NIH/NCATS) [E]

< [REDACTED] b6

Subject: Access Instructions: COVID-19 Clinical Trial Tracker

Good afternoon,

You can now access the **COVID-19 Clinical Trial Tracker**. For those who previously had access, NCATS has migrated the system from QlikView to QlikSense for improved functionality. This dashboard visualization is populated with curated data sent to NIH from the Operation Warp Speed team at the FDA. The curated data gives you access to all the reported COVID-19 clinical trials across the globe using public information from CT.gov and the WHO global database. This dashboard and underlying curated data are updated weekly by the FDA and the informatics team at NCATS. We hope you find this to be a valuable tool. We intend to set up a brief demo of the dashboard in the coming days. Please stay tuned for an email for that offering.

Please follow the attached instructions on how to access the tracker. If you have any questions or need assistance, please do not hesitate to reach out!

Best,
Sam

Samantha Jonson, MPS [E]
Special Assistant to the Director
National Center for Advancing Translational Sciences
National Institutes of Health
6701 Democracy Blvd., Room 990
Bethesda, MD 20892
(Use ZIP code 20817 for overnight mail or courier)
Office line: [REDACTED] b6
Cell: [REDACTED] b6
E-mail: [REDACTED] b6



National Center
for Advancing
Translational Sciences

COLLABORATE. INNOVATE. ACCELERATE.

From: Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6
Sent: Wednesday, August 12, 2020 5:25 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 ; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 Lane,
Cliff (NIH/NIAID) [E] [REDACTED] b6 ; Freire, Maria (FNIH) [T] [REDACTED] b6 >; Austin, Christopher
(NIH/NCATS) [E] [REDACTED] b6 Parker, Ashley (NIH/OD) [E] [REDACTED] b6 Anderson, James
(NIH/OD) [E] [REDACTED] b6 >
Cc: Jonson, Samantha (NIH/NCATS) [E] [REDACTED] b6 >; Cutillo, Christine (NIH/NCATS) [E]
< [REDACTED] b6 Dickens, Jim (NIH/NCATS) [C] [REDACTED] b6 Kurilla, Michael (NIH/NCATS) [E]
< [REDACTED] b6
Subject: COVID-19 Clinical Trial Tracker

Fellow War Room occupants,

As you know, in coordination with FDA/OWS, NCATS has developed a COVID-19 Clinical Trial Tracker of all reported COVID-19 clinical trial information in CT.gov and the WHO clinical trial registry. The data used to populate the dashboard is curated by FDA/OWS and updated information is sent to NCATS each week and we in turn update the Tracker. NCATS

GADB0000001983

has previously shared this tracker with senior NIH colleagues, and we have been working through issues FDA had with expanding beyond NIH. I'm delighted to report that we have received clearance with the FDA to provide access to our FNIH ACTIV colleagues and NIHers on the ACTIV EC. We do not plan on extending access to our pharma partners on the ACTIV EC due to resource limitations and policy concerns.

People who have current access to the Tracker, and the people who will now be added, are below.

COVID-19 Clinical Trial Tracker Access List

Current:	Francis Collins, Larry Tabak, Christopher Austin, Michael Kurilla, Hugh Auchincloss, Ashley Parker, Michelle Culp, Ellen Gadbois, Samantha Jonson, Jim Dickens, Trans NIH 2 Working Group, NCATS Informatics team
To be given:	External: David Wholley, Maria Freire, Joseph Menetski, Stacey Adam Internal: Anthony Fauci, Gary Gibbons

A separate email will be sent to those listed above with instructions on how to access the tracker. We hope that you take advantage of this very powerful resource and tool.

Thanks go to Sam Jonson, Mike Kurilla, Jim Dickens, and Christine Cutillo for their excellent work in creating the Tracker.

Please let me know if you have questions; any suggestions for improvements would also be welcome.

Chris

Christopher P. Austin, M.D.
Director



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for Advancing
Translational Sciences

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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 12/4/2020 9:11:42 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: Zeke's comment about ACTIV IRB

Don't know. Maybe they are following the lead of their bosses. 😞

From: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] > **b6**
Sent: Friday, December 4, 2020 4:07 PM
To: Culp, Michelle (NIH/OD) [E] < [REDACTED] > **b6**
Subject: RE: Zeke's comment about ACTIV IRB

And I wonder why Cliff and Amy don't just talk to each other if their people are in conflict.

From: Culp, Michelle (NIH/OD) [E] < [REDACTED] > **b6**
Sent: Friday, December 4, 2020 3:47 PM
To: Wholley, David (FNIH) [T] < [REDACTED] > **b6**
Cc: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] > **b6**
Subject: Zeke's comment about ACTIV IRB

David,
I'm interested in understanding where Zeke might have been going about the IRB review. I'm wondering if he thinking it would fall into the public health surveillance exception? OSP would be interested to know what was behind his question, if you know.
Thanks!
-Michelle

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/21/2020 8:02:35 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: IBs for ACTIV-2/3 mAb Agents

Yes, sorry both in ACTIV-2 and ACTIV-3.

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 | Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] <b6>
Sent: Wednesday, October 21, 2020 4:00 PM
To: Adam, Stacey (FNIH) [T] <b6>
Subject: RE: IBs for ACTIV-2/3 mAb Agents

Thanks—assume the same for both trials--

From: Adam, Stacey (FNIH) [T] <b6>
Sent: Wednesday, October 21, 2020 4:00 PM
To: Gadbois, Ellen (NIH/OD) [E] b6
Subject: RE: IBs for ACTIV-2/3 mAb Agents

Hi Ellen,

The two antibodies are to be used together in a cocktail.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 | Mobile: (b6

From: Gadbois, Ellen (NIH/OD) [E] b6 >
Sent: Wednesday, October 21, 2020 3:50 PM
To: Adam, Stacey (FNIH) [T] b6
Subject: RE: IBs for ACTIV-2/3 mAb Agents

Q on Brii—are the 2 antibodies to be used together, or is one for ACTIV-2 and one for ACTIV-3?
Thanks

From: Adam, Stacey (FNIH) [T] b6
Sent: Wednesday, October 21, 2020 3:37 PM

To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: IBs for ACTIV-2/3 mAb Agents

Thanks!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, October 21, 2020 3:34 PM
To: Adam, Stacey (FNIH) [T] b
Subject: RE: IBs for ACTIV-2/3 mAb Agents

Right.

From: Adam, Stacey (FNIH) [T] [REDACTED] b6
Sent: Wednesday, October 21, 2020 3:34 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: IBs for ACTIV-2/3 mAb Agents

Hi Ellen,

Happy to help. Also, just a reminder, these are VERY confidential, so please don't share them outside of the USG and better if not even outside of those working on ACTIV.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, October 21, 2020 3:30 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Subject: RE: IBs for ACTIV-2/3 mAb Agents

Thanks so much.
Ellen

From: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Sent: Wednesday, October 21, 2020 3:23 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Subject: IBs for ACTIV-2/3 mAb Agents

Hi Ellen,

I hope this will help.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Foundation for the National Institutes of Health

Direct: [REDACTED] b6 , Mobile: [REDACTED] b6

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID 19: fnih.org/pandemic



From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 10/20/2020 8:04:52 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Koniges, Ursula (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5ae2c3139654bc0b9b95718d516310b-konigesum]; Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0fb5e52c31a4-tuckerjm]
Subject: RE: for CW decision (in next day or so): different next steps on mAbs?

Agreed.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, October 20, 2020 1:57 PM
To: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Koniges, Ursula (NIH/OD) [E] <[REDACTED]> **b6**; Tucker, Jessica (NIH/OD) [E] <jessica.[REDACTED]> **b6**
Subject: for CW decision (in next day or so): different next steps on mAbs?

Carrie—see below. Sarah thinks that except for Lilly, NIAID doesn't have the information on the mAbs. Rather than have things get lost in translation, I propose that I let NIAID off of the hook (except for what they have on the Lilly product) and I work directly with Stacey Adam (FNIH) and Deloitte to figure out what is in the information already submitted for the other mAbs to ACTIV.

But I think we may still end up having to ask some or all of the companies if there was any HFT use. I am not sure whether it is a good or bad idea to have Deloitte emailing or calling the companies—I could take that on if you think that is better. Or we can cross that bridge later once I see the info we have.

Thanks,
Ellen

From: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Sent: Tuesday, October 20, 2020 1:31 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Ellen, to be honest I think Stacey (with support from Deloitte staff) is actually the best person to coordinate this. These questions are related to ACTIV2 and 3, and all these antibodies are coming in through ACTIV not NIAID. LY-CoV555 is the only antibody for which NIAID played a role in discovery. ACTIV has access to the information submitted by the companies (B's etc) and also has the company contacts for asking for more information. NIAID would have to dig for all this information...or ask Stacey for it.

I'm happy to discuss if you have concerns...feel free to call my cell [REDACTED] **b6** I'm free now until 3.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, October 20, 2020 12:56 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: FW: urgent for FC--can reply by 3:25 with any info?

Hi Sarah—thanks again for your quick help yesterday. Do you think the NIAID group can put this information together? I'm not sure who everyone is, and don't want to tell people what to do. I'm happy to play a role here, but am just not

sure if that would be useful or not. I copied Melinda because she is also good at coordinating responses and I could go to her with this request instead, if you want. I'm not sure it's fair to ask Stacey to do anything, although she may have good points of contacts at companies.

So appreciate any guidance you have.

Thanks again,

Ellen

From: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Sent: Monday, October 19, 2020 5:53 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>; Read, Sarah (NIH/NIAID) [E] <[REDACTED]>; Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]>
Cc: Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

I agree with Ellen. (And thanks, everyone, for jumping in on this!) Cheers, Carrie

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Monday, October 19, 2020 4:49 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]>; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>; Read, Sarah (NIH/NIAID) [E] <[REDACTED]>; Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]>
Cc: Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>; Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

b4

For the others, where NIH is not directly involved in R or

D, ask the company whether human fetal cells or tissues were used in product research or development and see what they say. (The companies will be getting this question too, so they should get an answer ready...)

Ellen

From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Monday, October 19, 2020 4:38 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>; Read, Sarah (NIH/NIAID) [E] <[REDACTED]>; Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]>
Cc: Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>; Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Ellen,

Just my humble opinion, but #1 is likely easy enough with the IBs, but #2 and #3 could be hard given the number of tests and all the independent testing contracted out. They might take some time unless we are okay with the company just giving us a yes or no answer and trusting them. Others may feel differently.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships

Direct: (b6 Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Monday, October 19, 2020 4:24 PM
To: Marovich, Mary (NIH/NIAID) [E] b6 >; Read, Sarah (NIH/NIAID) [E] b6
Tressler, Randall (NIH/NIAID) [E] b6 Eakin, Ann (NIH/NIAID) [E] < b6 >
Cc: Haskins, Melinda (NIH/NIAID) [E] b6 >; Adam, Stacey (FNIH) [T] b6 Wolinetz,
Carrie (NIH/OD) [E] < b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thank you everyone! Sorry about the rush. It seems likely that NIH is going to get more questions along these lines, so it would be great if you could keep digging, but at a more reasonable pace. I think we should know 1) whether the products were made in fetal cell lines, 2) whether there were assays done using fetal lines, 3) whether there was use of fetal tissue or cells in making a mouse as part of the research, and for any of those items, the source/reference of the info. Would it make sense to start a table? I am happy to help although you may have better ways of compiling the information on a NIAID system. Just let me know. Ellen

From: Wolinetz, Carrie (NIH/OD) [E] b6
Sent: Monday, October 19, 2020 4:13 PM
To: Marovich, Mary (NIH/NIAID) [E] < b6 Adam, Stacey (FNIH) [T] < b6 Read, Sarah
(NIH/NIAID) [E] b6 >; Gadbois, Ellen (NIH/OD) [E] < b6 Tressler, Randall
(NIH/NIAID) [E] b6 Eakin, Ann (NIH/NIAID) [E] b6
Cc: Haskins, Melinda (NIH/NIAID) [E] < b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

OK – just jumping in here. This info is useful for future reference, but the meeting it was to be used for is just about over, so the urgency is a little diminished; there's time to collect it.

From: Marovich, Mary (NIH/NIAID) [E] b6
Sent: Monday, October 19, 2020 4:10 PM
To: Adam, Stacey (FNIH) [T] < b6 Read, Sarah (NIH/NIAID) [E] < b6 >; Gadbois, Ellen
(NIH/OD) [E] b6 Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann
(NIH/NIAID) [E] b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] < b6 Haskins, Melinda (NIH/NIAID) [E]
b6
Subject: Re: urgent for FC--can reply by 3:25 with any info?

Thx Stacey - and do we know about the 2nd mAb in the cocktail?

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From: Adam, Stacey (FNIH) [T] b6
Sent: Monday, October 19, 2020 4:09:23 PM
To: Read, Sarah (NIH/NIAID) [E] b6 >; Gadbois, Ellen (NIH/OD) [E] b6
Marovich, Mary (NIH/NIAID) [E] < b6 Tressler, Randall (NIH/NIAID) [E]
b6 >; Eakin, Ann (NIH/NIAID) [E] b6 >

Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6 Haskins, Melinda (NIH/NIAID) [E]

b6

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi All,

Just responded to Ellen LY-CoV555 is manufactured in CHO (Chinese Hamster Ovary) cell line.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 Mobile: b6

From: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> b6

Sent: Monday, October 19, 2020 3:56 PM

To: Gadbois, Ellen (NIH/OD) [E] b6 Marovich, Mary (NIH/NIAID) [E] b6

Tressler, Randall (NIH/NIAID) [E] b6 Eakin, Ann (NIH/NIAID) [E] b6 >

Cc: Wolinetz, Carrie (NIH/OD) [E] b6 >; Haskins, Melinda (NIH/NIAID) [E]

b6 ; Adam, Stacey (FNIH) [T] <[REDACTED]> b6

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Copying Stacey as well. Stacey, who do you think would be the best contact at Lilly for this question (highlighted below)? Carl?

From: Gadbois, Ellen (NIH/OD) [E] b6

Sent: Monday, October 19, 2020 3:52 PM

To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> b6 Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> b6

Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]> b6 >

Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6 >; Haskins, Melinda (NIH/NIAID) [E]

<[REDACTED]> b6 >

Subject: RE: urgent for FC--can reply by 3:25 with any info?

FYI the NY Times reported:

<https://www.nytimes.com/2020/10/08/health/trump-covid-fetal-tissue.html?auth=login-email&login=email>

"Regeneron tested the antibodies against virus-like particles created using 293T human cells. The viral particles serve as a proxy for the live coronavirus; testing otherwise would require a lab with extremely high biosafety levels. (Eli Lilly, which also is manufacturing monoclonal antibodies, is using the same method.)"

See Figure 1 in methods paper cited in the Times article:

<https://www.sciencedirect.com/science/article/pii/S009286742030742X>

A SARS-CoV-2 Infection Model in Mice Demonstrates Protection by Neutralizing Antibodies

Figure 1. SARS CoV 2 Infection in Conventional Laboratory Strains of Mice and Expression of hACE2 after AdV Transduction

(C) HEK293 cells were transduced with AdV-hACE2-GFP. Flow cytometric analysis of hACE2 and GFP expression was analyzed at 4 and 10 h after AdV transduction. One of two experiments is shown.

Can Lilly confirm usage of HEK293 and was there any other human fetal cell use for that mAb, and do we know anything about the other mAbs lined up for ACTIV-2 or 3? (We already know about Regeneron.)

Thank you!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, October 19, 2020 3:43 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]>; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>;
Tressler, Randall (NIH/NIAID) [E] <[REDACTED]> Eakin, Ann (NIH/NIAID) [E] <[REDACTED]>
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks, all. Just to list them together: commonly used immortalized cell lines original from HFT and used for various purposes are PERC6, WI-38, MRC-5, and HEK293.

From: Read, Sarah (NIH/NIAID) [E]
Sent: Monday, October 19, 2020 3:42 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>;
Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]>
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Adding in Ann Eakin as well. Ann, see highlighted queries below.

From: Read, Sarah (NIH/NIAID) [E]
Sent: Monday, October 19, 2020 3:40 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]>
Tressler, Randall (NIH/NIAID) [E] <[REDACTED]>
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]>
Subject: RE: urgent for FC--can reply by 3:25 with any info?
Importance: High

Ellen, I apologize I just got off a call and am just seeing your note now. I don't know the answer to your query. I'm copying Mary Marovich and Randy Tressler who might know better than I.

Mary and Randy if you have knowledge of the cell line(s) used by Lilly please respond to Ellen.

Thanks

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, October 19, 2020 3:18 PM
To: Read, Sarah (NIH/NIAID) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Haskins, Melinda (NIH/NIAID) [E]

b6

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Just FYI WI-38 and MRC-5 are other old cell lines from human fetal tissue used in vaccine production and for other purposes—they are also immortalized.

From: Gadbois, Ellen (NIH/OD) [E]

Sent: Monday, October 19, 2020 3:17 PM

To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]>

Cc: Wolinetz, Carrie (NIH/OD) [E] [REDACTED] Haskins, Melinda (NIH/NIAID) [E]

b6

Subject: urgent for FC--can reply by 3:25 with any info?

Hi Sarah,

Sorry for the urgent request, but something is happening at 3:30 today and Dr. Collins would appreciate receiving any info we have on the use of human fetal cell lines (or human fetal tissue) in the development or production of monoclonal antibodies vs. COVID-19. I already sent what I have on the use of HEK293T cells by Regeneron. Do you know if Lilly is using HEK293 or any of the other old fetal cells lines for their monoclonal? Or do you know about the other companies with products being considered for ACTIV-2 or ACTIV-3?

Thanks,

Ellen Gadbois

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy

Office of Science Policy

Office of the Director

National Institutes of Health

Building 1 Suite 218

voice: [REDACTED]

fax: 301-402-0280



National Institutes of Health
Turning Discovery Into Health

GADB0000002118

From: Marovich, Mary (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BFD0192D165D4643ACCF6347728DBAEB-MAROVICHMA]
Sent: 10/21/2020 6:54:56 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tressler]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Haskins, Melinda (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545e01141619453bb4fc1dcde6c45887-haskinsm]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

That works.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, October 21, 2020 1:56 PM
To: Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> **b6** Eakin, Ann (NIH/NIAID) [E] <[REDACTED]> **b6**
Tressler, Randall (NIH/NIAID) [E] <[REDACTED]> **b6** Read, Sarah (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> **b6** Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks, Mary. Sarah suggested that you would be a good central NIAID contact for me on data about Lilly antibodies, so I'll follow up with you separately on those. I'll talk later today with Stacey about information that FNIH may have about the other products lined up for ACTIV-2 and 3.

Ellen

From: Marovich, Mary (NIH/NIAID) [E] **b6**
Sent: Monday, October 19, 2020 5:54 PM
To: Wolinetz, Carrie (NIH/OD) [E] **b6** >; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Adam, Stacey (FNIH) [T] **b6** >; Read, Sarah (NIH/NIAID) [E] **b6** >; Tressler, Randall (NIH/NIAID) [E] **b6**
Eakin, Ann (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Haskins, Melinda (NIH/NIAID) [E] **b6** >
Subject: Re: urgent for FC--can reply by 3:25 with any info?

Also their 2nd mAb is produced in CHO cells.

Mary

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From: Wolinetz, Carrie (NIH/OD) [E] **b6**
Sent: Monday, October 19, 2020 5:52 PM
To: Gadbois, Ellen (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Marovich, Mary (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Tressler, Randall (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]
Cc: Haskins, Melinda (NIH/NIAID) [E]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

I agree with Ellen. (And thanks, everyone, for jumping in on this!) Cheers, Carrie

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Sent: Monday, October 19, 2020 4:49 PM
To: Adam, Stacey (FNIH) [T] b6 ; Marovich, Mary (NIH/NIAID) [E] b6 ; Read, Sarah (NIH/NIAID) [E] b6 ; Tressler, Randall (NIH/NIAID) [E] b6 Eakin, Ann (NIH/NIAID) [E] < b6 >
Cc: Haskins, Melinda (NIH/NIAID) [E] b6 >; Wolinetz, Carrie (NIH/OD) [E] < b6 >
Subject: RE: urgent for FC--can reply by 3:25 with any info?

b4

For the others, where NIH is not directly involved in R or D, ask the company whether human fetal cells or tissues were used in product research or development and see what they say. (The companies will be getting this question too, so they should get an answer ready...)
Ellen

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Cc: Haskins, Melinda (NIH/NIAID) [E] < b6 > Wolinetz, Carrie (NIH/OD) [E] < b6 >
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Ellen,

Just my humble opinion, but #1 is likely easy enough with the IBs, but #2 and #3 could be hard given the number of tests and all the independent testing contracted out. They might take some time unless we are okay with the company just giving us a yes or no answer and trusting them. Others may feel differently.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 , Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] < b6 >
Sent: Monday, October 19, 2020 4:24 PM
To: Marovich, Mary (NIH/NIAID) [E] < b6 > Read, Sarah (NIH/NIAID) [E] < b6 >
Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann (NIH/NIAID) [E] b6 >
Cc: Haskins, Melinda (NIH/NIAID) [E] b6 >; Adam, Stacey (FNIH) [T] b6 > Wolinetz, Carrie (NIH/OD) [E] b6 >
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thank you everyone! Sorry about the rush. It seems likely that NIH is going to get more questions along these lines, so it would be great if you could keep digging, but at a more reasonable pace. I think we should know 1) whether the products were made in fetal cell lines, 2) whether there were assays done using fetal lines, 3) whether there was use of fetal tissue or cells in making a mouse as part of the research, and for any of those items, the source/reference of the info. Would it make sense to start a table? I am happy to help although you may have better ways of compiling the information on a NIAID system. Just let me know. Ellen

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Sent: Monday, October 19, 2020 4:13 PM
To: Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> b6 Adam, Stacey (FNIH) [T] b6 >; Read, Sarah (NIH/NIAID) [E] b6 >; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6 Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]> b6
Cc: Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

OK – just jumping in here. This info is useful for future reference, but the meeting it was to be used for is just about over, so the urgency is a little diminished; there's time to collect it.

From: Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> b6
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To: Adam, Stacey (FNIH) [T] <[REDACTED]> b6 Read, Sarah (NIH/NIAID) [E] <[REDACTED]> b6 Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6 Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann (NIH/NIAID) [E] b6
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6 >; Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> b6
Subject: Re: urgent for FC--can reply by 3:25 with any info?

Thx Stacey - and do we know about the 2nd mAb in the cocktail?

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From: Adam, Stacey (FNIH) [T] b6
Sent: Monday, October 19, 2020 4:09:23 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> b6 ; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6 ; Marovich, Mary (NIH/NIAID) [E] <[REDACTED]> b6 Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann (NIH/NIAID) [E] <[REDACTED]> b6
Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6 Haskins, Melinda (NIH/NIAID) [E] <[REDACTED]> b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi All,

Just responded to Ellen LY-CoV555 is manufactured in CHO (Chinese Hamster Ovary) cell line.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: ([REDACTED]) b6 Mobile: [REDACTED] b6

From: Read, Sarah (NIH/NIAID) [E] b6
Sent: Monday, October 19, 2020 3:56 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 ; Marovich, Mary (NIH/NIAID) [E] b6 ;
Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann (NIH/NIAID) [E] b6
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 >; Haskins, Melinda (NIH/NIAID) [E]
b6 >; Adam, Stacey (FNIH) [T] b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Copying Stacey as well. Stacey, who do you think would be the best contact at Lilly for this question (highlighted below)? Carl?

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Monday, October 19, 2020 3:52 PM
To: Read, Sarah (NIH/NIAID) [E] b6 >; Marovich, Mary (NIH/NIAID) [E] b6
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Cc: Wolinetz, Carrie (NIH/OD) [E] b6 . Haskins, Melinda (NIH/NIAID) [E]
< b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

FYI the NY Times reported:

<https://www.nytimes.com/2020/10/08/health/trump-covid-fetal-tissue.html?auth=login-email&login=email>
"Regeneron tested the antibodies against virus-like particles created using 293T human cells. The viral particles serve as a proxy for the live coronavirus; testing otherwise would require a lab with extremely high biosafety levels. (Eli Lilly, which also is manufacturing monoclonal antibodies, is using the same method.)"

See Figure 1 in methods paper cited in the Times article:

<https://www.sciencedirect.com/science/article/pii/S009286742030742X>

A SARS-CoV-2 Infection Model in Mice Demonstrates Protection by Neutralizing Antibodies

Figure 1. SARS-CoV-2 Infection in Conventional Laboratory Strains of Mice and Expression of hACE2 after AdV Transduction

(C) HEK293 cells were transduced with AdV-hACE2-GFP. Flow cytometric analysis of hACE2 and GFP expression was analyzed at 4 and 10 h after AdV transduction. One of two experiments is shown.

Can Lilly confirm usage of HEK293 and was there any other human fetal cell use for that mAb, and do we know anything about the other mAbs lined up for ACTIV-2 or 3? (We already know about Regeneron.)

Thank you!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, October 19, 2020 3:43 PM
To: Read, Sarah (NIH/NIAID) [E] b6 >; Marovich, Mary (NIH/NIAID) [E] b6 >;
Tressler, Randall (NIH/NIAID) [E] b6 Eakin, Ann (NIH/NIAID) [E] b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 >; Haskins, Melinda (NIH/NIAID) [E]

b6 >

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks, all. Just to list them together: commonly used immortalized cell lines original from HFT and used for various purposes are PERC6, WI-38, MRC-5, and HEK293.

From: Read, Sarah (NIH/NIAID) [E] < b6 >

Sent: Monday, October 19, 2020 3:42 PM

To: Gadbois, Ellen (NIH/OD) [E] < b6 >; Marovich, Mary (NIH/NIAID) [E] < b6 >;
Tressler, Randall (NIH/NIAID) [E] < b6 >; Eakin, Ann (NIH/NIAID) [E] < b6 >;
Cc: Wolinetz, Carrie (NIH/OD) [E] < b6 >; Haskins, Melinda (NIH/NIAID) [E] < b6 >

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Adding in Ann Eakin as well. Ann, see highlighted queries below.

From: Read, Sarah (NIH/NIAID) [E]

Sent: Monday, October 19, 2020 3:40 PM

To: Gadbois, Ellen (NIH/OD) [E] < b6 >; Marovich, Mary (NIH/NIAID) [E] < b6 >;
Tressler, Randall (NIH/NIAID) [E] < b6 >;
Cc: Wolinetz, Carrie (NIH/OD) [E] < b6 >; Haskins, Melinda (NIH/NIAID) [E] < b6 >

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Importance: High

Ellen, I apologize I just got off a call and am just seeing your note now. I don't know the answer to your query. I'm copying Mary Marovich and Randy Tressler who might know better than I.

Mary and Randy if you have knowledge of the cell line(s) used by Lilly please respond to Ellen.

Thanks

From: Gadbois, Ellen (NIH/OD) [E] < b6 >

Sent: Monday, October 19, 2020 3:18 PM

To: Read, Sarah (NIH/NIAID) [E] < b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] < b6 >; Haskins, Melinda (NIH/NIAID) [E] < b6 >

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Just FYI WI-38 and MRC-5 are other old cell lines from human fetal tissue used in vaccine production and for other purposes—they are also immortalized.

From: Gadbois, Ellen (NIH/OD) [E]

Sent: Monday, October 19, 2020 3:17 PM

To: Read, Sarah (NIH/NIAID) [E] < b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] < b6 >; Haskins, Melinda (NIH/NIAID) [E] < b6 >

Subject: urgent for FC--can reply by 3:25 with any info?

Hi Sarah,

Sorry for the urgent request, but something is happening at 3:30 today and Dr. Collins would appreciate receiving any info we have on the use of human fetal cell lines (or human fetal tissue) in the development or production of monoclonal antibodies vs. COVID-19. I already sent what I have on the use of HEK293T cells by Regeneron. Do you know if Lily is using HEK293 or any of the other old fetal cells lines for their monoclonal? Or do you know about the other companies with products being considered for ACTIV-2 or ACTIV-3?

Thanks,
Ellen Gadbois

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280



From: Jonson, Samantha (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE2F69369D654BEF89B0D39B145D69A7-JONSONSG]
Sent: 10/21/2020 6:46:46 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Access Instructions: COVID-19 Clinical Trial Tracker

Hi Ellen,

Was just emailing you, too! Glad you were able to get in. It looks like you were a first time user so we had to add you to the stream on our end. Let me know if you have any questions.

Best,
Sam

Samantha Jonson, MPS [E]
Dissemination and Implementation Strategy Lead
National Center for Advancing Translational Sciences
National Institutes of Health
6701 Democracy Blvd., Room 990
Bethesda, MD 20892
(Use ZIP code 20817 for overnight mail or courier)
Office line: b6
Cell: (b6
E-mail: b6



National Center
for Advancing
Translational Sciences

COLLABORATE. INNOVATE. ACCELERATE.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, October 21, 2020 2:41 PM
To: Jonson, Samantha (NIH/NCATS) [E] < b6
Cc: Cutillo, Christine (NIH/NCATS) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6
Subject: RE: Access Instructions: COVID-19 Clinical Trial Tracker

Disregard—I've got it now.
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, October 21, 2020 12:08 PM
To: Jonson, Samantha (NIH/NCATS) [E] b6
Cc: Cutillo, Christine (NIH/NCATS) [E] b6 ; Parker, Ashley (NIH/OD) [E] b6
Subject: RE: Access Instructions: COVID-19 Clinical Trial Tracker

GADB0000002183

Hi Samantha,

I am trying to access the Clinical Trial tracker, and while I can log in, there isn't any content in there. However, I never saw an Affiliate HHS PIV card certificate among the options—I just chose the certificate that I always do for other things. Can you help?

Thanks,

Ellen



From: Jonson, Samantha (NIH/NCATS) [E]

b6

Sent: Thursday, August 13, 2020 3:49 PM

To: Collins, Francis (NIH/OD) [E]

b6

Tabak, Lawrence (NIH/OD) [E]

b6

>> Lane,

Cliff (NIH/NIAID) [E] <

b6

Freire, Maria (FNIH) [T] <

b6

Wholley, David (FNIH) [T]

<

b6

Menetski, Joseph (FNIH) [T]

b6

Adam, Stacey (FNIH) [T]

b6

Culp, Michelle (NIH/OD) [E] <

b6

Gadbois, Ellen (NIH/OD) [E] <

b6

>; Parker,

Ashley (NIH/OD) [E]

b6

>; Gibbons, Gary (NIH/NHLBI) [E]

b6

Cc: Austin, Christopher (NIH/NCATS) [E]

b6

>; Kurilla, Michael (NIH/NCATS) [E]

b6

; Dickens, Jim (NIH/NCATS) [C] <

b6

; Cutillo, Christine (NIH/NCATS) [E]

Subject: Access Instructions: COVID-19 Clinical Trial Tracker

Good afternoon,

GADB0000002183

You can now access the **COVID-19 Clinical Trial Tracker**. For those who previously had access, NCATS has migrated the system from QlikView to QlikSense for improved functionality. This dashboard visualization is populated with curated data sent to NIH from the Operation Warp Speed team at the FDA. The curated data gives you access to all the reported COVID-19 clinical trials across the globe using public information from CT.gov and the WHO global database. This dashboard and underlying curated data are updated weekly by the FDA and the informatics team at NCATS. We hope you find this to be a valuable tool. We intend to set up a brief demo of the dashboard in the coming days. Please stay tuned for an email for that offering.

Please follow the attached instructions on how to access the tracker. If you have any questions or need assistance, please do not hesitate to reach out!

Best,
Sam

Samantha Jonson, MPS [E]
Special Assistant to the Director
National Center for Advancing Translational Sciences
National Institutes of Health
6701 Democracy Blvd., Room 990
Bethesda, MD 20892
(Use ZIP code 20817 for overnight mail or courier)
Office line: b6
Cell: b6 6
E-mail: b6



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for Advancing
Translational Sciences

COLLABORATE. INNOVATE. ACCELERATE.

From: Austin, Christopher (NIH/NCATS) [E] b6
Sent: Wednesday, August 12, 2020 5:25 PM
To: Collins, Francis (NIH/OD) [E] b6 >, Tabak, Lawrence (NIH/OD) [E] < b6 Lane,
Cliff (NIH/NIAID) [E] b6 >; Freire, Maria (FNIH) [T] b6 >; Austin, Christopher
(NIH/NCATS) [E] b6 >; Parker, Ashley (NIH/OD) [E] < b6 Anderson, James
(NIH/OD) [E] < b6
Cc: Jonson, Samantha (NIH/NCATS) [E] b6 >, Cutillo, Christine (NIH/NCATS) [E]
b6 Dickens, Jim (NIH/NCATS) [C] b6 >; Kurilla, Michael (NIH/NCATS) [E]
>
Subject: COVID-19 Clinical Trial Tracker

Fellow War Room occupants,

As you know, in coordination with FDA/OWS, NCATS has developed a COVID-19 Clinical Trial Tracker of all reported COVID-19 clinical trial information in CT.gov and the WHO clinical trial registry. The data used to populate the dashboard is curated by FDA/OWS and updated information is sent to NCATS each week and we in turn update the Tracker. NCATS has previously shared this tracker with senior NIH colleagues, and we have been working through issues FDA had with expanding beyond NIH. I'm delighted to report that we have received clearance with the FDA to provide access to our FNIH ACTIV colleagues and NIHers on the ACTIV EC. We do not plan on extending access to our pharma partners on the ACTIV EC due to resource limitations and policy concerns.

People who have current access to the Tracker, and the people who will now be added, are below.

COVID-19 Clinical Trial Tracker Access List

Current:	Francis Collins, Larry Tabak, Christopher Austin, Michael Kurilla, Hugh Auchincloss, Ashley Parker, Michelle Culp, Ellen Gadbois, Samantha Jonson, Jim Dickens, Trans NIH 2 Working Group, NCATS Informatics team
To be given:	External: David Wholley, Maria Freire, Joseph Menetski, Stacey Adam Internal: Anthony Fauci, Gary Gibbons

A separate email will be sent to those listed above with instructions on how to access the tracker. We hope that you take advantage of this very powerful resource and tool.

Thanks go to Sam Jonson, Mike Kurilla, Jim Dickens, and Christine Cutillo for their excellent work in creating the Tracker.

Please let me know if you have questions; any suggestions for improvements would also be welcome.

Chris

Christopher P. Austin, M.D.
Director



National Center
for Advancing
Translational Sciences

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Connect with us!: <https://ncats.nih.gov/connect>

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/19/2020 8:18:16 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerl]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]
CC: Haskins, Melinda (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545e01141619453bb4fc1dcde6c45887-haskinsm]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Carrie,

Sorry we were not fast enough. Had to scan the IB for the product. I don't have the IB for LY CoV016, but I do have a text out to Carl Garner who Sarah referred to earlier.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 | Mobile: b6

From: Wolinetz, Carrie (NIH/OD) [E] <b6>
Sent: Monday, October 19, 2020 4:13 PM
To: Marovich, Mary (NIH/NIAID) [E] <b6> Adam, Stacey (FNIH) [T] <b6> Read, Sarah (NIH/NIAID) [E] <b6> Gadbois, Ellen (NIH/OD) [E] <b6> Tressler, Randall (NIH/NIAID) [E] <b6> Eakin, Ann (NIH/NIAID) [E] <b6>
Cc: Haskins, Melinda (NIH/NIAID) [E] <b6>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

OK – just jumping in here. This info is useful for future reference, but the meeting it was to be used for is just about over, so the urgency is a little diminished; there's time to collect it.

From: Marovich, Mary (NIH/NIAID) [E] <b6>
Sent: Monday, October 19, 2020 4:10 PM
To: Adam, Stacey (FNIH) [T] <b6> Read, Sarah (NIH/NIAID) [E] <b6> Gadbois, Ellen (NIH/OD) [E] <b6> >; Tressler, Randall (NIH/NIAID) [E] <b6> Eakin, Ann (NIH/NIAID) [E] <b6>
Cc: Wolinetz, Carrie (NIH/OD) [E] <b6> Haskins, Melinda (NIH/NIAID) [E]

b6

Subject: Re: urgent for FC--can reply by 3:25 with any info?

Thx Stacey - and do we know about the 2nd mAb in the cocktail?

Get [Outlook for iOS](#)

From: Adam, Stacey (FNIH) [T] b6
Sent: Monday, October 19, 2020 4:09:23 PM
To: Read, Sarah (NIH/NIAID) [E] b6 >; Gadbois, Ellen (NIH/OD) [E] b6 ;
Marovich, Mary (NIH/NIAID) [E] b6 >; Tressler, Randall (NIH/NIAID) [E]
b6 >; Eakin, Ann (NIH/NIAID) [E] b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 Haskins, Melinda (NIH/NIAID) [E]
b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi All,

Just responded to Ellen LY-CoV555 is manufactured in CHO (Chinese Hamster Ovary) cell line.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 | Mobile: b6

From: Read, Sarah (NIH/NIAID) [E] < b6
Sent: Monday, October 19, 2020 3:56 PM
To: Gadbois, Ellen (NIH/OD) [E] b >; Marovich, Mary (NIH/NIAID) [E] < b6 >;
Tressler, Randall (NIH/NIAID) [E] b6 ; Eakin, Ann (NIH/NIAID) [E] b6 >
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 >; Haskins, Melinda (NIH/NIAID) [E]
b6 Adam, Stacey (FNIH) [T] b6
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Copying Stacey as well. Stacey, who do you think would be the best contact at Lilly for this question (highlighted below)? Carl?

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Monday, October 19, 2020 3:52 PM
To: Read, Sarah (NIH/NIAID) [E] b6 >; Marovich, Mary (NIH/NIAID) [E] b6 ,
Tressler, Randall (NIH/NIAID) [E] b6 >; Eakin, Ann (NIH/NIAID) [E] < b6
Cc: Wolinetz, Carrie (NIH/OD) [E] < b6 Haskins, Melinda (NIH/NIAID) [E]
b6 >
Subject: RE: urgent for FC--can reply by 3:25 with any info?

FYI the NY Times reported:

<https://www.nytimes.com/2020/10/08/health/trump-covid-fetal-tissue.html?auth=login-email&login=email>

GADB0000002184

"Regeneron tested the antibodies against virus-like particles created using 293T human cells. The viral particles serve as a proxy for the live coronavirus; testing otherwise would require a lab with extremely high biosafety levels. (Eli Lilly, which also is manufacturing monoclonal antibodies, is using the same method.)"

See Figure 1 in methods paper cited in the Times article:

<https://www.sciencedirect.com/science/article/pii/S009286742030742X>

A SARS-CoV-2 Infection Model in Mice Demonstrates Protection by Neutralizing Antibodies

Figure 1. SARS-CoV-2 Infection in Conventional Laboratory Strains of Mice and Expression of hACE2 after AdV Transduction

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Can Lilly confirm usage of HEK293 and was there any other human fetal cell use for that mAb, and do we know anything about the other mAbs lined up for ACTIV-2 or 3? (We already know about Regeneron.)

Thank you!

From: Gadbois, Ellen (NIH/OD) [E]

Sent: Monday, October 19, 2020 3:43 PM

To: Read, Sarah (NIH/NIAID) [E] <b6> Marovich, Mary (NIH/NIAID) [E] <b6>
Tressler, Randall (NIH/NIAID) [E] <b6> Eakin, Ann (NIH/NIAID) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E] <b6> Haskins, Melinda (NIH/NIAID) [E]
b6 >

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thanks, all. Just to list them together: commonly used immortalized cell lines original from HFT and used for various purposes are PERC6, WI-38, MRC-5, and HEK293.

From: Read, Sarah (NIH/NIAID) [E] <b6>

Sent: Monday, October 19, 2020 3:42 PM

To: Gadbois, Ellen (NIH/OD) [E] <b6> Marovich, Mary (NIH/NIAID) [E] <b6>
Tressler, Randall (NIH/NIAID) [E] <b6> Eakin, Ann (NIH/NIAID) [E] <b6>
Cc: Wolinetz, Carrie (NIH/OD) [E] <b6> >; Haskins, Melinda (NIH/NIAID) [E]
b6

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Adding in Ann Eakin as well. Ann, see highlighted queries below.

From: Read, Sarah (NIH/NIAID) [E]

Sent: Monday, October 19, 2020 3:40 PM

To: Gadbois, Ellen (NIH/OD) [E] <b6> Marovich, Mary (NIH/NIAID) [E] <b6> >;
Tressler, Randall (NIH/NIAID) [E] <b6>
Cc: Wolinetz, Carrie (NIH/OD) [E] <b6> >; Haskins, Melinda (NIH/NIAID) [E]
b6 >

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Importance: High

Ellen, I apologize I just got off a call and am just seeing your note now. I don't know the answer to your query. I'm copying Mary Marovich and Randy Tressler who might know better than I.

Mary and Randy if you have knowledge of the cell line(s) used by Lilly please respond to Ellen.

Thanks

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, October 19, 2020 3:18 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]> b6
Cc: Wolinetz, Carrie (NIH/OD) [E] b6 ; Haskins, Melinda (NIH/NIAID) [E]
b6 >
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Just FYI WI-38 and MRC-5 are other old cell lines from human fetal tissue used in vaccine production and for other purposes—they are also immortalized.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, October 19, 2020 3:17 PM
To: Read, Sarah (NIH/NIAID) [E] b6
Cc: Wolinetz, Carrie (NIH/OD) [E] ; Haskins, Melinda (NIH/NIAID) [E]
<[REDACTED]> b6
Subject: urgent for FC--can reply by 3:25 with any info?

Hi Sarah,

Sorry for the urgent request, but something is happening at 3:30 today and Dr. Collins would appreciate receiving any info we have on the use of human fetal cell lines (or human fetal tissue) in the development or production of monoclonal antibodies vs. COVID-19. I already sent what I have on the use of HEK293T cells by Regeneron. Do you know if Lilly is using HEK293 or any of the other old fetal cell lines for their monoclonal? Or do you know about the other companies with products being considered for ACTIV-2 or ACTIV-3?

Thanks,
Ellen Gadbois

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: [REDACTED] b6
fax: 301 402 0280



National Institutes of Health
Turning Discovery into Health

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/21/2020 5:42:52 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Yep, will do!

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: **b6** Mobile: **b6**

From: Gadbois, Ellen (NIH/OD) [E] <**b6**>
Sent: Wednesday, October 21, 2020 1:04 PM
To: Adam, Stacey (FNIH) [T] <**b6**>
Subject: RE: urgent for FC--can reply by 3:25 with any Info?

No problem. Yes, let's talk at 3. Do you want to skype call me then?
Thanks

From: Adam, Stacey (FNIH) [T] **b6**
Sent: Wednesday, October 21, 2020 12:14 PM
To: Gadbois, Ellen (NIH/OD) [E] **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Ellen,

Apologies for the slow reply and for now needing to ask to move our time to 3pm if possible?

Understood on not reaching out to companies. I assume that the majority of the manufacturing data can be found in the Investigator's Brochures which I have many of and could get the rest of what you need. The testing done will also be in the IBs, but the problem is they may not have a deep enough detail to tell you if an embryonically generated cell line or mouse was used in the particular assay. Not sure. I have not tried to look this type of information up on a compound after the fact before. Honestly, if the information is super critical, we might have to go directly to the companies eventually, though I understand that is not desired at this point.

As for the recap submissions, unfortunately not all of the companies got to the level of detail that you will need. We can pull those files for you as well, but I just worry you aren't going to find what you need.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: **b6** Mobile: **b6**

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, October 21, 2020 10:09 AM
To: Adam, Stacey (FNIH) [T] **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

I have a hard stop at 4:45 but I'll hold the time. Just to clarify—at this point, I really only want to look at information that ACTIV has in hand on the products, and not ask anyone to ask companies any questions (at least at this point). I will do this myself, but probably need guidance to figure out what to look at. The Redcap submissions seem to be an obvious place to start and so I will ask NCATS for access. Perhaps we can talk later about what else I could review.

There's no hard deadline that I know of right now, but NIH will keep getting questions on this topic, so I need to have some kind of answer. (We have already been asked with regards to vaccines from Congress and HHS.)

Thanks

From: Adam, Stacey (FNIH) [T] **b6**
Sent: Wednesday, October 21, 2020 8:30 AM
To: Gadbois, Ellen (NIH/OD) [E] **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Ellen,

How about 4:30 after our group check in? Would that work for you?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: ([REDACTED]) **b6** Mobile: ([REDACTED]) **b6**

From: Gadbois, Ellen (NIH/OD) [E] **b6**
Sent: Wednesday, October 21, 2020 8:14 AM
To: Adam, Stacey (FNIH) [T] **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Stacey do you have time for a quick phone call today? I'm free from about 8:45-9:15, then 11-noon, and flexible after 1 p.m.
Thanks,
Ellen

From: Adam, Stacey (FNIH) [T] **b6**
Sent: Tuesday, October 20, 2020 9:17 PM
To: Gadbois, Ellen (NIH/OD) [E] **b6**
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi Ellen,

What is the timeline that we would need to compile this information in? And how thorough would we need to document each assay for each agent, or could the company's word be good enough?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b6), Mobile: (b6)

From: Gadbois, Ellen (NIH/OD) [E] (b6)
Sent: Tuesday, October 20, 2020 6:44 PM
To: Adam, Stacey (FNIH) [T] <(b6)>
Subject: Re: urgent for FC--can reply by 3:25 with any info?

Hi again Stacey,
Sarah told me that other than the Lilly product, she doesn't think NIAID staff can sort out possible HFT uses for the other mAbs without coming to you to see what has been submitted as part of ACTIV. I hate to add to your workload so am wondering if someone can orient me to where the info lives and I could look (maybe with help from Deloitte?). If necessary I can think about contacting companies, but that could get dicey so I would like to see first what ACTIV already knows.
Please advise on what you think would work.
Thanks,
Ellen

Sent from my iPhone

On Oct 19, 2020, at 4:37 PM, Adam, Stacey (FNIH) [T] (b6) > wrote:

Hi Ellen,

Just my humble opinion, but #1 is likely easy enough with the IBs, but #2 and #3 could be hard given the number of tests and all the independent testing contracted out. They might take some time unless we are okay with the company just giving us a yes or no answer and trusting them. Others may feel differently.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b6) | Mobile: (b6)

From: Gadbois, Ellen (NIH/OD) [E] (b6)
Sent: Monday, October 19, 2020 4:24 PM
To: Marovich, Mary (NIH/NIAID) [E] <(b6)>; Read, Sarah (NIH/NIAID) [E] (b6); Tressler, Randall (NIH/NIAID) [E] <(b6)>; Eakin, Ann (NIH/NIAID) [E] (b6)
Cc: Haskins, Melinda (NIH/NIAID) [E] (b6); Adam, Stacey (FNIH) [T]

< [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Thank you everyone! Sorry about the rush. It seems likely that NIH is going to get more questions along these lines, so it would be great if you could keep digging, but at a more reasonable pace. I think we should know 1) whether the products were made in fetal cell lines, 2) whether there were assays done using fetal lines, 3) whether there was use of fetal tissue or cells in making a mouse as part of the research, and for any of those items, the source/reference of the info. Would it make sense to start a table? I am happy to help although you may have better ways of compiling the information on a NIAID system. Just let me know. Ellen

From: Wolinetz, Carrie (NIH/OD) [E] [b6] >
Sent: Monday, October 19, 2020 4:13 PM
To: Marovich, Mary (NIH/NIAID) [E] [b6] >; Adam, Stacey (FNIH) [T]
< [b6] Read, Sarah (NIH/NIAID) [E] [b6] Gadbois, Ellen (NIH/OD) [E]
< [b6] Tressler, Randall (NIH/NIAID) [E] < [b6] Eakin, Ann
(NIH/NIAID) [E] [b6]
Cc: Haskins, Melinda (NIH/NIAID) [E] [b6]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

OK – just jumping in here. This info is useful for future reference, but the meeting it was to be used for is just about over, so the urgency is a little diminished; there's time to collect it.

From: Marovich, Mary (NIH/NIAID) [E] [b6]
Sent: Monday, October 19, 2020 4:10 PM
To: Adam, Stacey (FNIH) [T] [b6] >; Read, Sarah (NIH/NIAID) [E] < [b6]
Gadbois, Ellen (NIH/OD) [E] < [b6] Tressler, Randall (NIH/NIAID) [E]
[b6] Eakin, Ann (NIH/NIAID) [E] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E] [b6] >; Haskins, Melinda (NIH/NIAID) [E]
[b6] >
Subject: Re: urgent for FC--can reply by 3:25 with any info?

Thx Stacey - and do we know about the 2nd mAb in the cocktail?

Get Outlook for iOS

From: Adam, Stacey (FNIH) [T] < [b6]
Sent: Monday, October 19, 2020 4:09:23 PM
To: Read, Sarah (NIH/NIAID) [E] < [b6] Gadbois, Ellen (NIH/OD) [E]
[b6] ; Marovich, Mary (NIH/NIAID) [E] [b6] Tressler, Randall
(NIH/NIAID) [E] < [b6] Eakin, Ann (NIH/NIAID) [E] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E] [b6] Haskins, Melinda (NIH/NIAID) [E]
< [b6]
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Hi All,

Just responded to Ellen LY-CoV555 is manufactured in CHO (Chinese Hamster Ovary) cell line.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Read, Sarah (NIH/NIAID) [E] [REDACTED] b6

Sent: Monday, October 19, 2020 3:56 PM

To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6> . Marovich, Mary (NIH/NIAID) [E]

[REDACTED] b6 >; Tressler, Randall (NIH/NIAID) [E] [REDACTED] b6 >; Eakin, Ann (NIH/NIAID) [E] [REDACTED] b6

Cc: Wolinetz, Carrie (NIH/OD) [E] [REDACTED] b6 Haskins, Melinda (NIH/NIAID) [E]

[REDACTED] b6 >; Adam, Stacey (FNIH) [T] <[REDACTED] b6>

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Copying Stacey as well. Stacey, who do you think would be the best contact at Lilly for this question (highlighted below)? Carl?

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6

Sent: Monday, October 19, 2020 3:52 PM

To: Read, Sarah (NIH/NIAID) [E] <[REDACTED] b6> Marovich, Mary (NIH/NIAID) [E]

[REDACTED] b6 >; Tressler, Randall (NIH/NIAID) [E] [REDACTED] b6 Eakin, Ann (NIH/NIAID) [E] <[REDACTED] b6>

Cc: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED] b6> Haskins, Melinda (NIH/NIAID) [E]

[REDACTED] b6

Subject: RE: urgent for FC--can reply by 3:25 with any info?

FYI the NY Times reported:

<https://www.nytimes.com/2020/10/08/health/trump-covid-fetal-tissue.html?auth-login-email&login=email>

"Regeneron tested the antibodies against virus-like particles created using 293T human cells. The viral particles serve as a proxy for the live coronavirus; testing otherwise would require a lab with extremely high biosafety levels. (Eli Lilly, which also is manufacturing monoclonal antibodies, is using the same method.)"

See Figure 1 in methods paper cited in the Times article:

<https://www.sciencedirect.com/science/article/pii/S009286742030742X>

A SARS-CoV-2 Infection Model in Mice Demonstrates Protection by Neutralizing Antibodies

Figure 1. SARS-CoV-2 Infection in Conventional Laboratory Strains of Mice and Expression of hACE2 after AdV Transduction

(C) HEK293 cells were transduced with AdV-hACE2-GFP. Flow cytometric analysis of hACE2 and GFP expression was analyzed at 4 and 10 h after AdV transduction. One of two experiments is shown.

Can Lilly confirm usage of HEK293 and was there any other human fetal cell use for that mAb, and do we know anything about the other mAbs lined up for ACTIV-2 or 3? (We already know about Regeneron.)

Thank you!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, October 19, 2020 3:43 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]@b6.gov>; Marovich, Mary (NIH/NIAID) [E]
[REDACTED]@b6.gov>; Tressler, Randall (NIH/NIAID) [E] [REDACTED]@b6.gov Eakin, Ann
(NIH/NIAID) [E] <[REDACTED]@b6.gov>
Cc: Wolinetz, Carrie (NIH/OD) [E] [REDACTED]@b6.gov>; Haskins, Melinda (NIH/NIAID) [E]
<[REDACTED]@b6.gov>
Subject: RE: urgent for FC--can reply by 3.25 with any info?

Thanks, all. Just to list them together: commonly used immortalized cell lines original from HFT and used for various purposes are PERC6, WI-38, MRC-5, and HEK293.

From: Read, Sarah (NIH/NIAID) [E] [REDACTED]@b6.gov
Sent: Monday, October 19, 2020 3:42 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]@b6.gov> Marovich, Mary (NIH/NIAID) [E]
[REDACTED]@b6.gov>; Tressler, Randall (NIH/NIAID) [E] <[REDACTED]@b6.gov> Eakin, Ann
(NIH/NIAID) [E] <[REDACTED]@b6.gov>
Cc: Wolinetz, Carrie (NIH/OD) [E] [REDACTED]@b6.gov> Haskins, Melinda (NIH/NIAID) [E]
<[REDACTED]@b6.gov>
Subject: RE: urgent for FC--can reply by 3:25 with any info?

Adding in Ann Eakin as well. Ann, see highlighted queries below.

From: Read, Sarah (NIH/NIAID) [E]
Sent: Monday, October 19, 2020 3:40 PM
To: Gadbois, Ellen (NIH/OD) [E] [REDACTED]@b6.gov>; Marovich, Mary (NIH/NIAID) [E]
<[REDACTED]@b6.gov> Tressler, Randall (NIH/NIAID) [E] [REDACTED]@b6.gov>
Cc: Wolinetz, Carrie (NIH/OD) [E] [REDACTED]@b6.gov>; Haskins, Melinda (NIH/NIAID) [E]
[REDACTED]@b6.gov>
Subject: RE: urgent for FC--can reply by 3:25 with any info?
Importance: High

Ellen, I apologize I just got off a call and am just seeing your note now. I don't know the answer to your query. I'm copying Mary Marovich and Randy Tressler who might know better than I.

Mary and Randy if you have knowledge of the cell line(s) used by Lilly please respond to Ellen

Thanks

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED]@b6.gov>
Sent: Monday, October 19, 2020 3:18 PM
To: Read, Sarah (NIH/NIAID) [E] <[REDACTED]@b6.gov>
Cc: Wolinetz, Carrie (NIH/OD) [E] [REDACTED]@b6.gov>; Haskins, Melinda (NIH/NIAID) [E]

< [REDACTED] b6

Subject: RE: urgent for FC--can reply by 3:25 with any info?

Just FYI WI-38 and MRC-5 are other old cell lines from human fetal tissue used in vaccine production and for other purposes—they are also immortalized.

From: Gadbois, Ellen (NIH/OD) [E]

Sent: Monday, October 19, 2020 3:17 PM

To: Read, Sarah (NIH/NIAID) [E] < [REDACTED] b6

Cc: Wolinetz, Carrie (NIH/OD) [E] < [REDACTED] b6 Haskins, Melinda (NIH/NIAID) [E]

[REDACTED] b6

Subject: urgent for FC--can reply by 3:25 with any info?

Hi Sarah,

Sorry for the urgent request, but something is happening at 3:30 today and Dr. Collins would appreciate receiving any info we have on the use of human fetal cell lines (or human fetal tissue) in the development or production of monoclonal antibodies vs. COVID-19. I already sent what I have on the use of HEK293T cells by Regeneron. Do you know if Lily is using HEK293 or any of the other old fetal cell lines for their monoclonal? Or do you know about the other companies with products being considered for ACTIV-2 or ACTIV-3?

Thanks,

Ellen Gadbois

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy

Office of Science Policy

Office of the Director

National Institutes of Health

Building 1 Suite 218

voice: [REDACTED] b6

fax: 301-402-0280

<image001.png>

GADB0000002224

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 9/21/2020 2:53:30 PM
To: Williams, Rebecca (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ce81afae21d42e5bc0ec6e8d920c1f9-williamsre]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Dobbins, Heather (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88aefe47febc458a96438393871202f3-dobbinshd]
CC: Johnson, Lenora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=059e53e386aa42fea27c7e17a4cc3cd7-johnslen]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: finding ACTIV trials in ClinicalTrials.gov search

Becky,
Thank you!
Best,
Michelle

From: Williams, Rebecca (NIH/NLM/NCBI) [E] <[REDACTED]> **b6**
Sent: Monday, September 21, 2020 9:31 AM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**; Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**; Dobbins, Heather (NIH/NLM/NCBI) [E] <[REDACTED]> **b6**
Cc: Johnson, Lenora (NIH/NHLBI) [E] <[REDACTED]> **b6**; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: finding ACTIV trials in ClinicalTrials.gov search

Hi Michelle –

Just following up on this thread a bit late. The key way for people to be able to find the ACTIV trials through a search of the term “ACTIV” would be to ensure the ACTIV naming is present in informative fields in the study record. Currently, it only seems to be appearing in the Secondary ID. I am not certain if it should be part of the Collaborators field (identifying the ACTIV partnership as a group) and/or as part of the Brief Title and Official Title in the study record following the numbering outlined below.

Also, wanted to note that there may be some confusion about current naming and easy identification as other acronyms have also been assigned to the studies (e.g., NCT04501978 is referred to as TICO). Thus, it may be worthwhile for the ACTIV team to consider how they might better facilitate easier understanding/recognition through the naming of the trials themselves. Any changes to the study records will need to be coordinated with the listed study sponsor (e.g., NIAID).

Best regards,
Becky

From: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Sent: Tuesday, September 01, 2020 5:37 PM
To: Williams, Rebecca (NIH/NLM/NCBI) [E] <[REDACTED]> **b6**; Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**; Dobbins, Heather (NIH/NLM/NCBI) [E] <[REDACTED]> **b6**
Cc: Johnson, Lenora (NIH/NHLBI) [E] <[REDACTED]> **b6**; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: finding ACTIV trials in ClinicalTrials.gov search

Hi Becky,

I will let Michelle weigh in, as well, but just for reference, here are the NCT #s. Lenora, can you make sure I classified the ACTIV-4 trials correctly?

ACTIV-1: TBD
ACTIV-2: NCT04518410
ACTIV-3: NCT04501978
ACTIV-4b (Outpatient): NCT04498273
ACTIV-4a (Inpatient): NCT04505774
ACTIV-4c (Convalescent): TBD
ACTIV-5: TBD

Also, just to answer your first question, yes, we would like these trials to come up higher in the search algorithm when "ACTIV" is searched in CT.gov.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: b6 | Mobile: b6

From: Williams, Rebecca (NIH/NLM/NCBI) [E] <b6>
Sent: Tuesday, September 1, 2020 5:29 PM
To: Culp, Michelle (NIH/OD) [E] b6 Dobbins, Heather (NIH/NLM/NCBI) [E]
<b6>
Cc: Adam, Stacey (FNIH) [T] b6 Johnson, Lenora (NIH/NHLBI) [E] b6 Gadbois,
Ellen (NIH/OD) [E] <b6>
Subject: RE: finding ACTIV trials in ClinicalTrials.gov search

Hi Michelle:

(Patti – moving you to bcc: to spare you the back and forth but will let you know where this lands)

Can you clarify the request. Are you wanting these studies to be higher on search results when you specifically search for the term "ACTIV"? If so, we can take a closer look at the study records and make recommendations for how you might modify the study record to improve their ranking by relevancy.

We may be able to add a bullet to the peach box to link to the ACTIV studies. We'd need to see whether we could identify a good algorithmic search approach for the link or if we'd need it to be by NCT number. This also relates to the above.

Can you send us the definitive list of NCT numbers for ACTIV studies currently registered?

Also, Heather Dobbins did have a productive call with some folks from NIAID and the ACTIV-3 study team on considerations for registration and results reporting. However, we haven't heard back from them since that

call (we know they are busy!). If there is a way we may be able to help more directly in ACTIV efforts we'd be happy to do so

Thanks,
Becky

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Tuesday, September 01, 2020 2:47 PM
To: Brennan, Patti (NIH/NLM) [E] < b6 Williams, Rebecca (NIH/NLM/NCBI) [E]
b6 ; Dobbins, Heather (NIH/NLM/NCBI) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6 >; Johnson, Lenora (NIH/NHLBI) [E] b6 Gadbois,
Ellen (NIH/OD) [E] < b6
Subject: finding ACTIV trials in ClinicalTrials.gov search

Dear Patti, Becky and Heather,

The ACTIV study teams would like to learn how to make the ACTIV trials be more easily found in a ClinicalTrials.gov search.

They would like to know if there is a way to prioritize the ACTIV trials in a ClinicalTrials.gov search so that ACTIV studies come up higher (or at the top) in search result.

- What terms can be added to the registration record to make ACTIV trials higher up on the search result?
- Is it possible to have the ACTIV trials linked in the peach colored box or near the top of the list of the COVID-19 search result? (see paste below.)
- Who on your team can the speak to about this?

Thank you for your help!

All the best,
Michelle

Home > Search Results

Modify Search

Start Over

79 Studies found for COVID-19; NIH, U.S. Fed

Also searched for COVID and SARS-CoV-2 [See Search Details](#)Applied Filters: ☒ Funding: NIH ☒ Funding: U.S. Federal

Your search included COVID-19

Learn more about clinical studies related to COVID-19

- [ClinicalTrials.gov](#) Federally funded clinical studies related to COVID-19
- [WHO Trial Registry Network](#) COVID-19 studies from the ICTRP data base
- [NIH COVID-19 Treatment Guidelines](#)
- [ClinicalTrials.gov](#) [View all listed COVID-19 Studies](#) (562)

List By Topic On Map Search Details

Hide Filters

Filters

Clear

Status

Recruitment

Not yet recruiting

Recruiting

Waiting for enrollment

Showing 1 to 79 studies 10 studies per page

Show Map > X-RAYS

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1			Phase 1/2a Study of the Efficacy and Safety of the SARS-CoV-2 Vaccine, mRNA-1273, in Healthy Adults	<ul style="list-style-type: none">SARS-CoV-2COVID-19	<ul style="list-style-type: none">Drug: HydroxychloroquineDrug: AzithromycinDrug: Placebo	<ul style="list-style-type: none">San Francisco, CASan Francisco, CaliforniaUnited States
2			Phase 1/2a Study of the Efficacy and Safety of the COVID-19 Vaccine, mRNA-1273, in Healthy Adults	<ul style="list-style-type: none">COVID-19		<ul style="list-style-type: none">NIH Clinical Research Unit (CRU)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/24/2020 8:29:08 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Mar a (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: FOR INPUT: BuzzFeed News: ACTIV meeting

Hi Ashley. We will handle this issue as it affects the WGs. thanks

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Monday, August 24, 2020 2:22 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>
Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Subject: FW: FOR INPUT: BuzzFeed News: ACTIV meeting

Hi Francis et al.

Given the leak with the vaccines WG meeting that took place on 8/14, maybe there is a need to reaffirm ACTIV members confidentiality? This is not specifically directed at the inquiry below referencing a statement made by Paul but flagging given this is such a sensitive topic among others that should not be discussed outside of the WGs to my understanding.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, August 24, 2020 1:50 PM
To: Fine, Amanda (NIH/OD) [E] <[REDACTED]>
Cc: Myles, Renate (NIH/OD) [E] <[REDACTED]> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]>
Subject: RE: FOR INPUT: BuzzFeed News: ACTIV meeting

Hi Amanda,

The ACTIV vaccines WG will meet tomorrow for an ad-hoc meeting but this is a closed meeting not open to the public. Given the leak of information provided from a vaccine meeting that took place on 8/14, FNIH, ACTIV members and others are concerned that information discussed is not being kept confidential.

Thanks,
Ashley

From: Fine, Amanda (NIH/OD) [E] <[REDACTED]>
Sent: Monday, August 24, 2020 1:22 PM

To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6** Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> **b6**
Subject: FOR INPUT: BuzzFeed News: ACTIV meeting

Hi Ashley-

Not sure if you are still out, but see below question from BuzzFeed—do you know if this meeting is public?

Thanks!
Amanda

From: Dan Vergano <[REDACTED]> **b6**
Sent: Monday, August 24, 2020 1:15 PM
To: Fine, Amanda (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> **b6**
Subject: BuzzFeed News: ACTIV meeting

Amanda,

Paul Offit just said on a JAMA webcast that the ACTIV group is meeting tomorrow to discuss OWS candidate vaccines. Is this meeting open to the public? I don't see a web link posted.

Dan

cc: Emma

**On CARES Act work sharing program through 2020 |*

Dan Vergano

Science Desk (DC)

b6

BuzzFeed News

111 E. 18th St., 13th Floor

NY, NY 10003

Send secure tips -- [contact.buzzfeed.com](https://www.buzzfeed.com/contact)

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 9/2/2020 8:15:55 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Williams, Rebecca (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ce81afae21d42e5bc0ec6e8d920c1f9-williamsre]; Dobbins, Heather (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88aefe47febc458a96438393871202f3-dobbinshd]
CC: Johnson, Lenora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=059e53e386aa42fea27c7e17a4cc3cd7-johnslen]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: finding ACTIV trials in ClinicalTrials.gov search

Becky and Heather,

For the ACTIV studies, will there be a *single* NCT number for each ACTIV trials?

Since these are master protocols with multiple product sponsors, we just want to be sure we're providing the correct NCT # or #s.

ACTIV-1: TBD
ACTIV-2: NCT04518410
ACTIV-3: NCT04501978
ACTIV-4b (Outpatient): NCT04498273
ACTIV-4a (Inpatient): NCT04505774
ACTIV-4c (Convalescent): TBD
ACTIV-5: TBD

Thank you!

-Michelle

From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Tuesday, September 1, 2020 5:37 PM
To: Williams, Rebecca (NIH/NLM/NCBI) [F] <[REDACTED]> Culp, Michelle (NIH/OD) [E] <[REDACTED]> Dobbins, Heather (NIH/NLM/NCBI) [E] <[REDACTED]>
Cc: Johnson, Lenora (NIH/NHLBI) [E] <[REDACTED]> Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Subject: RE: finding ACTIV trials in ClinicalTrials.gov search

Hi Becky,

I will let Michelle weigh in, as well, but just for reference, here are the NCT #s. Lenora, can you make sure I classified the ACTIV-4 trials correctly?

ACTIV-1: TBD
ACTIV-2: NCT04518410
ACTIV-3: NCT04501978
ACTIV-4b (Outpatient): NCT04498273
ACTIV-4a (Inpatient): NCT04505774
ACTIV-4c (Convalescent): TBD
ACTIV-5: TBD

Also, just to answer your first question, yes, we would like these trials to come up higher in the search algorithm when "ACTIV" is searched in CT.gov.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 , Mobile: b6

From: Williams, Rebecca (NIH/NLM/NCBI) [E] b6
Sent: Tuesday, September 1, 2020 5:29 PM
To: Culp, Michelle (NIH/OD) [E] b6 Dobbins, Heather (NIH/NLM/NCBI) [E]
< b6
Cc: Adam, Stacey (FNIH) [T] < b6 Johnson, Lenora (NIH/NHLBI) [E] < b6 Gadbois,
Ellen (NIH/OD) [E] < b6
Subject: RE: finding ACTIV trials in ClinicalTrials.gov search

Hi Michelle:

(Patti – moving you to bcc: to spare you the back and forth but will let you know where this lands)

Can you clarify the request. Are you wanting these studies to be higher on search results when you specifically search for the term "ACTIV"? If so, we can take a closer look at the study records and make recommendations for how you might modify the study record to improve their ranking by relevancy.

We may be able to add a bullet to the peach box to link to the ACTIV studies. We'd need to see whether we could identify a good algorithmic search approach for the link or if we'd need it to be by NCT number. This also relates to the above.

Can you send us the definitive list of NCT numbers for ACTIV studies currently registered?

Also, Heather Dobbins did have a productive call with some folks from NIAID and the ACTIV-3 study team on considerations for registration and results reporting. However, we haven't heard back from them since that call (we know they are busy!). If there is a way we may be able to help more directly in ACTIV efforts we'd be happy to do so.

Thanks,
Becky

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Tuesday, September 01, 2020 2:47 PM
To: Brennan, Patti (NIH/NLM) [E] < b6 Williams, Rebecca (NIH/NLM/NCBI) [E]
< b6 Dobbins, Heather (NIH/NLM/NCBI) [E] < b6
Cc: Adam, Stacey (FNIH) [T] b6 Johnson, Lenora (NIH/NHLBI) [E] b6 ; Gadbois,
Ellen (NIH/OD) [E] < b6
Subject: finding ACTIV trials in ClinicalTrials.gov search

Dear Patti, Becky and Heather,

The ACTIV study teams would like to learn how to make the ACTIV trials be more easily found in a ClinicalTrials.gov search.

They would like to know if there is a way to prioritize the ACTIV trials in a ClinicalTrials.gov search so that ACTIV studies come up higher (or at the top) in search result.

- What terms can be added to the registration record to make ACTIV trials higher up on the search result?
- Is it possible to have the ACTIV trials linked in the peach colored box or near the top of the list of the COVID-19 search result? (see paste below.)
- Who on your team can the speak to about this?

Thank you for your help!

All the best,
Michelle

U.S. National Library of Medicine
ClinicalTrials.gov

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79 Studies found for **COVID-19 (NH, U.S. Fed)**
Also searched for **COVID** and **SARS-CoV-2** [See Search Details](#)
Applied Filters: ☒ Funding: NIH ☒ Funding: U.S. Federal

Your search included **COVID-19**
Learn more about clinical studies related to COVID-19

- [ClinicalTrials.gov](#) Federally funded clinical studies related to COVID-19
- [WHO Trial Registry Network](#) COVID-19 studies from the WHO database
- [NIH COVID-19 research priorities](#)
- [ClinicalTrials.gov](#) [ClinicalTrials.gov COVID-19 studies page](#)

List By Topic On Map Search Details

Hide Filters

Showing 1 to 2 of 79 results

Filters

Clear

Status

Recruitment

- 1 Not yet recruiting
- 1 Recruiting

Tracking by location

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1			COVID-19 treatment	<ul style="list-style-type: none">• SARS-CoV 2• COVID-19	<ul style="list-style-type: none">• Drug: hydroxychloroquine• Drug: Azithromycin• Drug: Paxlovid oral tablet	<ul style="list-style-type: none">• San Francisco VA• San Francisco, California• United States
2	LI	Recruiting	Serological Surveillance for COVID-19 in Central North Carolina	<ul style="list-style-type: none">• COVID-19		<ul style="list-style-type: none">• NCI/NCI Clinical Research Institute

From: Tucker, Jessica (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BAF4AE78D90412DBEFBFFB5E52C31A4-TUCKERJM]
Sent: 9/4/2020 2:08:29 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Got it.

From: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] > **b6**
Sent: Friday, September 4, 2020 10:08 AM
To: Tucker, Jessica (NIH/OD) [E] < [REDACTED] > **b6**
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Thanks.

ACTIV is a different section and Michelle/Lauren/Ashley & I will write it. (We've already done a detailed outline.)

I don't know anything about COVID All of Us testing so I am not putting anything in on that.

I will email Tyrone now.

From: Tucker, Jessica (NIH/OD) [E] < [REDACTED] > **b6**
Sent: Friday, September 4, 2020 10:03 AM
To: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] > **b6**
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

This seems fine. What was the outcome re: the ACTIV/COVID testing topic? Sorry, I'm not keeping up.

From: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] > **b6**
Sent: Friday, September 4, 2020 9:53 AM
To: Tucker, Jessica (NIH/OD) [E] < [REDACTED] > **b6**
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Do you want to review?

From: Tucker, Jessica (NIH/OD) [E] < [REDACTED] > **b6**
Sent: Friday, September 4, 2020 9:45 AM
To: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] > **b6**
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

OK, thanks. Please feel free to send all this stuff directly sounds like Tyrone is requesting input by 12 PM today (or COB today, depending on whether you go by the subject line or the e-mail itself).

From: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] > **b6**
Sent: Thursday, September 3, 2020 11:46 AM
To: Tucker, Jessica (NIH/OD) [E] < [REDACTED] > **b6**
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Yes we can point to some material for that.

From: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, September 3, 2020 10:50 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Subject: FW: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Defer to you re: Regenerative Medicine.

From: Berger, Adam (NIH/OD) [E] b6
Sent: Thursday, September 3, 2020 10:16 AM
To: Spady, Tyrone (NIH/OD) [E] <[REDACTED]> b6 Bayha, Ryan (NIH/OD) [E] <[REDACTED]> b6 >; Diggs, Susan (NIH/OD) [E] <[REDACTED]> b6 Fennington, Kelly (NIH/OD) [E] <[REDACTED]> b6 Isaacman-Beck, Jesse (NIH/OD) [E] <[REDACTED]> b6 ; Jorgenson, Lyric (NIH/OD) [E] <[REDACTED]> b6 Koniges, Ursula (NIH/OD) [E] <[REDACTED]> b6 Paine, Taunton (NIH/OD) [E] <[REDACTED]> b6 >; Rohrbaugh, Mark (NIH/OD) [E] <[REDACTED]> b6 >; Tucker, Jessica (NIH/OD) [E] b6 Wolinetz, Carrie (NIH/OD) [E] b6 Gadbois, Ellen (NIH/OD) [E] b6
Cc: Creery, Jessica (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

In looking at the full doc, there may be a few others to flag for OSP:

- Regenerative Medicine
- Research stewardship (OEPR, OLPA, OPA) Capitalizing
 - Updates on Implementation of Foundations for Evidence-Based Policymaking Act
 - Portfolio Analysis projects
 - Implementation of 21st Century Cures Act

We manage a report on clinical trials due under 21CCA I am attaching the last report that was transmitted to Congress on April 17, 2019. The next is due April 18, 2021 and is currently in development. I will leave it to you to determine whether it should be included (please let me know the answer here for future asks).

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892

b6 | b6



National Institutes of Health
Turning Discovery Into Health

From: Spady, Tyrone (NIH/OD) [E] b6
Sent: Wednesday, September 2, 2020 7:00 PM
To: Bayha, Ryan (NIH/OD) [E] b6 >, Berger, Adam (NIH/OD) [E] <[REDACTED]> b6 Diggs, Susan (NIH/OD) [E] <[REDACTED]> b6 Fennington, Kelly (NIH/OD) [E] b6 >; Isaacman-Beck, Jesse (NIH/OD) [E] <[REDACTED]> b6 Jorgenson, Lyric (NIH/OD) [E] <[REDACTED]> b6 Koniges, Ursula (NIH/OD) [E] <[REDACTED]> b6 >; Paine, Taunton (NIH/OD) [E] b6 >; Rohrbaugh, Mark (NIH/OD) [E] <[REDACTED]> b6 >; Tucker, Jessica (NIH/OD) [E] b6 Wolinetz, Carrie (NIH/OD) [E] b6 Gadbois, Ellen (NIH/OD) [E] b6
Cc: Creery, Jessica (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Hi all:

It looks like some of you might not have access to the Teams site. As work-arounds, I'm attaching the full OD CJ outline and please send your additions to me and Jessica Creery. We can upload for you.

Cheers,
T-

From: Spady, Tyrone (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, September 2, 2020 5:47 PM
To: Bayha, Ryan (NIH/OD) [E] <[REDACTED]>; Berger, Adam (NIH/OD) [E] <[REDACTED]>; Diggs, Susan (NIH/OD) [E] <[REDACTED]>; Fennington, Kelly (NIH/OD) [E] <[REDACTED]>; Isaacman-Beck, Jesse (NIH/OD) [E] <[REDACTED]>; Jorgenson, Lyric (NIH/OD) [E] <[REDACTED]>; Koniges, Ursula (NIH/OD) [E] <[REDACTED]>; Paine, Taunton (NIH/OD) [E] <[REDACTED]>; Rohrbaugh, Mark (NIH/OD) [E] <[REDACTED]>; Spady, Tyrone (NIH/OD) [E] <[REDACTED]>; Tucker, Jessica (NIH/OD) [E] <[REDACTED]>; Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>; Gadbois, E len (NIH/OD) [E] <[REDACTED]>
Cc: Creery, Jessica (NIH/OD) [E] <[REDACTED]>
Subject: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Hi all:

IMOD has issued a call for source material (reports, websites, formal announcements, etc...) for the OD Congressional Justification narrative (see below). Some of you may have already provided your contributions. If so, please let me know. We've listed the topics where OSP might have source materials to add. Please add any relevant source material on the subjects listed below (Full doc: [OD CJ Outline](#)) to the Teams folder named "Narrative Source Material" by COB on Friday, September 4th. Let me know if you have any questions.

OSP relevant subjects

- **BRAIN Initiative updates**
- **Accelerating Medicines Partnerships**
- **NIH efforts on Data Science and Artificial Intelligence**
 - Data sharing policies
 - Harnessing Data Science for Health Discovery and Innovation in Africa
 - Artificial Intelligence for Biomedical Excellence (AIBLE) program
 - Artificial Intelligence to address chronic disease
 - Collaboration with NASEM on Behavioral Ontologies
 - Updating MeSH terms
- **Rigor and Reproducibility**
 - ACD Working Group on Enhancing Reproducibility and Rigor in Animal Research
- **Program Portraits**
 - All of Us COVID-19 Testing, highlighting the Electronic Health Record Data survey to provide researchers with easy to use data on how participants are experiencing COVID-19 while maintaining privacy
 - **Strengthening Anti-Harassment Policies at NIH, updates from the ACD Working Group, implementation of new policies, and support for continued growth and development**
 - Updating the NIH-wide Strategic Plan, a trans-NIH effort guided by the OD to outline the NIH vision for biomedical research, opportunities for scientific exploration, and address new challenges for the next five years.

Cheers,
Tyrone

From: Landis, Erica (NIH/OD) [E] <[REDACTED]> b6
Sent: Tuesday, September 1, 2020 5:09 PM
To: Culhane, Ned (NIH/OD) [E] <[REDACTED]> b6; Hentges, Justin (NIH/OD) [E] <[REDACTED]> b6
Heath-Mason, Matthew (NIH/OD) [E] <[REDACTED]> b6; Le Fauve, Charlene (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Kawazoe, Robin (NIH/OD) [E] <[REDACTED]> b6; Spady, Tyrone (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Creery, Jessica (NIH/OD) [E] <[REDACTED]> b6; Noursi, Samia (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Morris, Patricia (NIH/NICHD) [E] <[REDACTED]> b6; Luetkemeier, Erin (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Klock, Kevin (FNIH) [T] <[REDACTED]> b6; Edghill Spano, Yvette (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Espinoza, Tasha (NIH/OD) [E] <[REDACTED]> b6; Morris, Kathryn (NIH/OD) [E] <[REDACTED]> b6
<[REDACTED]> b6; Myles, Renate (NIH/OD) [E] <[REDACTED]> b6; Burklow, John (NIH/OD) [E] <[REDACTED]> b6
<[REDACTED]> b6; Peterman Cross, Wilma (NIH/OD) [E] <[REDACTED]> b6; Thurn, Anne (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Kosub, David (NIH/OD) [E] <[REDACTED]> b6; Columbus, Megan (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Rabin, Elise (NIH/OD) [E] <[REDACTED]> b6; Owens, Roland (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Murray, Darryl (NIH/OD) [E] <[REDACTED]> b6; Shorback, Janet (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Stevens, Mark (NIH/OD) [E] <[REDACTED]> b6; Newman, Patricia (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Spencer, Elizabeth (NIH/OD) [E] <[REDACTED]> b6; Ekweani, Elonna (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Vonkollmar, Desiree (NIH/OD) [E] <[REDACTED]> b6; Courchesne, Stephanie (NIH/OD) [E] <[REDACTED]> b6
[E] <[REDACTED]> b6; Fennington, Kelly (NIH/OD) [E] <[REDACTED]> b6; Spaniol, Erin (NIH/OD) [E] <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; Baker, Rebecca (NIH/OD) [E] <[REDACTED]> b6
Cc: Mazzucco, Anna (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: Request: Source material for OD CJ Narrative draft

Dear all,

Thank you to those who have already provided source material for the OD Congressional Justification narrative. If you have not had a chance to yet, please add any relevant source material on the subjects listed in the OD CJ Outline to the Teams folder named "Narrative Source Material" by COB on Friday, September 4th.

Please feel free to reach out with any questions you have.

Very best,
Erica

Erica G. Landis, PhD
AAAS Science & Technology Policy Fellow
Immediate Office of the Director
National Institutes of Health
A: Building 1, Room 114
P: [REDACTED] b6

From: "Landis, Erica (NIH/OD) [E]" <[REDACTED]> b6
Date: Monday, August 24, 2020 at 12:04 PM
To: "Culhane, Ned (NIH/OD) [E]" <[REDACTED]> b6; "Hentges, Justin (NIH/OD) [E]" <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; "Heath-Mason, Matthew (NIH/OD) [E]" <[REDACTED]> b6; "Le Fauve, Charlene (NIH/OD) [E]" <[REDACTED]> b6; "Kawazoe, Robin (NIH/OD) [E]" <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; "Spady, Tyrone (NIH/OD) [E]" <[REDACTED]> b6; "Creery, Jessica (NIH/OD) [E]" <[REDACTED]> b6
[REDACTED] <[REDACTED]> b6; "Noursi, Samia (NIH/OD) [E]" <[REDACTED]> b6; "Morris, Patricia (NIH/OD) [E]" <[REDACTED]> b6

(NIH/NICHD) [E]" b6 >, "Luetkemeier, Erin (NIH/OD) [E]" b6
 "Klock, Kevin (FNIH) [T]" < b6 "Edghill Spano, Yvette (NIH/OD) [E]"
 b6 >, "Espinoza, Tasha (NIH/OD) [E]" < b6 "Morris, Kathryn
 (NIH/OD) [E]" b6 , "Myles, Renate (NIH/OD) [E]" b6 >, "Burklow,
 John (NIH/OD) [E]" < b6 "Peterman Cross, Wilma (NIH/OD) [E]"
 <petermaw@mail.nih.gov>, "Thurn, Anne (NIH/OD) [E]" b6 "Kosub, David (NIH/OD) [E]"
 < b6 "Columbus, Megan (NIH/OD) [E]" b6 "Rabin, Elise (NIH/OD)
 [E]" < b6 "Owens, Roland (NIH/OD) [E]" < b6 "Murray, Darryl (NIH/OD)
 [E]" < b6 "Shorback, Janet (NIH/OD) [E]" < b6 "Stevens, Mark
 (NIH/OD) [E]" b6 "Newman, Patricia (NIH/OD) [E]" < b6
 "Spencer, Elizabeth (NIH/OD) [E]" b6 "Ekweani, Elonna (NIH/OD) [E]"
 b6 >, "Vonkolimar, Desiree (NIH/OD) [E]" b6 >, "Courchesne,
 Stephanie (NIH/OD) [E]" b6 "Fennington, Kelly (NIH/OD) [E]"
 b6 "Spaniol, Erin (NIH/OD) [E]" < b6 "Baker, Rebecca (NIH/OD) [E]"
 b6

Cc: Anna Mazzucco < b6

Subject: Request: Source material for OD CJ Narrative draft

Dear all,

Thank you for all of your help in developing the OD Congressional Justification outline. Please see below a request for our next step.

ASK: Please submit any relevant source material on the subjects listed in the [OD CJ Outline](#) to the Teams folder named "[Narrative Source Material](#)" by **COB on Friday, September 4th**.

Background and Process: We greatly appreciate your help in developing the OD Congressional Justification outline for FY22. As the FY22 CJ Outline moves through the OLPA review process, we would like to begin collecting source material for the CJ Narrative to support the initial drafting process. IMOD will be taking the first pass at writing the Narrative section, the source material you contribute will be used to inform the writing process. For topics to submit source material on, please refer to the blue text in the CJ outline which indicates which OD Offices have played a role in each topic. Source material can include previously written or new reports, press releases, analyses, or any other documents which describe the program or topic. Once the Narrative is drafted, we will distribute it to you for your review before submission to OLPA.

For a reminder on the timeline for the OD CJ, please refer to the [Timeline](#) tab in Teams.

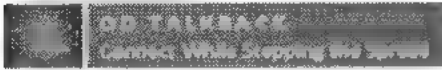
Please let us know if you have any questions or concerns. We appreciate you taking the time to provide feedback. Thank you in advance for your input!

Much appreciation,
 Erica

Erica G. Landis, PhD
 AAAS Science & Technology Policy Fellow
 Immediate Office of the Director
 National Institutes of Health

A: Building 1, Room 114

P* b6



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/12/2020 9:30:04 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: Fwd: COVID-19 Clinical Trial Tracker

FYI

Begin forwarded message:

From: "Austin, Christopher (NIH/NCATS) [E]" <[REDACTED]> **b6**
Date: August 12, 2020 at 5:24:37 PM EDT
To: "Collins, Francis (NIH/OD) [E]" <[REDACTED]> **b6** "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> **b6** "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED]> **b6** "Freire, Maria (FNIH) [T]" <[REDACTED]> **b6** "Austin, Christopher (NIH/NCATS) [E]" <[REDACTED]> **b6** "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> **b6** "Anderson, James (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Jonson, Samantha (NIH/NCATS) [E]" <[REDACTED]> **b6** "Cutillo, Christine (NIH/NCATS) [E]" <[REDACTED]> **b6** "Dickens, Jim (NIH/NCATS) [C]" <[REDACTED]> **b6** "Kurilla, Michael (NIH/NCATS) [E]" <[REDACTED]> **b6**
Subject: COVID-19 Clinical Trial Tracker

Fellow War Room occupants,

As you know, in coordination with FDA/OWS, NCATS has developed a COVID-19 Clinical Trial Tracker of all reported COVID-19 clinical trial information in [CT.gov](#) and the WHO clinical trial registry. The data used to populate the dashboard is curated by FDA/OWS and updated information is sent to NCATS each week and we in turn update the Tracker. NCATS has previously shared this tracker with senior NIH colleagues, and we have been working through issues FDA had with expanding beyond NIH. I'm delighted to report that we have received clearance with the FDA to provide access to our FNIH ACTIV colleagues and NIHers on the ACTIV EC. We do not plan on extending access to our pharma partners on the ACTIV EC due to resource limitations and policy concerns.

People who have current access to the Tracker, and the people who will now be added, are below.

COVID-19 Clinical Trial Tracker Access List

Current:	Francis Collins, Larry Tabak, Christopher Austin, Michael Kurilla, Hugh Auchincloss, Ashley Parker, Michelle Culp, Ellen Gadbois, Samantha Jonson, Jim Dickens, Trans NIH 2 Working Group, NCATS Informatics team
To be given:	External: David Wholley, Maria Freire, Joseph Menetski, Stacey Adam Internal: Anthony Fauci, Gary Gibbons

A separate email will be sent to those listed above with instructions on how to access the tracker. We hope that you take advantage of this very powerful resource and tool.

Thanks go to Sam Jonson, Mike Kurilla, Jim Dickens, and Christine Cutillo for their excellent work in creating the Tracker.

Please let me know if you have questions; any suggestions for improvements would also be welcome.

Chris

Christopher P. Austin, M.D.
Director



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/1/2020 6:23:25 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Johnson, Lenora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=059e53e386aa42fea27c7e17a4cc3cd7-johnslen]
Subject: RE: Follow-up on Prioritization within CT.gov

Thanks, Michelle!

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 Mobile: b6

From: Culp, Michelle (NIH/OD) [E] <b6>
Sent: Tuesday, September 1, 2020 2:23 PM
To: Adam, Stacey (FNIH) [T] <b6> Gadbois, Ellen (NIH/OD) [E] <b6>
Cc: Johnson, Lenora (NIH/NHLBI) [E] <b6>
Subject: RE: Follow-up on Prioritization within CT.gov

I'll reach out to NLM.

From: Adam, Stacey (FNIH) [T] b6
Sent: Tuesday, September 1, 2020 2:22 PM
To: Gadbois, Ellen (NIH/OD) [E] <b6>
Cc: Culp, Michelle (NIH/OD) [E] b6 >; Johnson, Lenora (NIH/NHLBI) [E] <b6>
Subject: RE: Follow-up on Prioritization within CT.gov

Thanks, Ellen,

This sounds like a good starting plan. Michelle, would you mind queuing this up for your next call with Patti and let us know how we should proceed from there?

I will reach out to Renate on the other item.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 | Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Tuesday, September 1, 2020 2:01 PM

GADB0000002481

To: Adam, Stacey (FNIH) [T] < [REDACTED] b6 >
Cc: Culp, Michelle (NIH/OD) [E] [REDACTED] b6 ; Johnson, Lenora (NIH/NHLBI) [E] [REDACTED] b6 >
Subject: RE: Follow-up on Prioritization within CT.gov

OK. So maybe if Michelle can ask Patti for a POC at NLM, you can run these various ideas past that person for the CT.gov side of things. (I'm happy to be on the call or contact that person if you would like me to.)

Separate from that, Renate can of course say whether she wants links from the NIH website. (I think it would be good because otherwise it is hard to figure out what trials are what with all of the similar names...)

From: Adam, Stacey (FNIH) [T] < [REDACTED] b6 >
Sent: Tuesday, September 1, 2020 1:50 PM
To: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] b6 >
Cc: Culp, Michelle (NIH/OD) [E] [REDACTED] b6 ; Johnson, Lenora (NIH/NHLBI) [E] < [REDACTED] b6 >
Subject: RE: Follow-up on Prioritization within CT.gov

Thanks, Ellen,

I appreciate you playing around with this. Your second and third searches were the ones I had done and was hoping to improve, so Michelle if you could ask if NLM has any suggestions that would be terrific.

Ellen, for your other suggestion about the links to the trials in CT.gov on the main page of the ACTIV NIH Clinical Therapeutics webpage would be terrific. I was unsure if that was allowed given that Renate had not already added the links. I can see if they would be amenable to adding the links to the page. I know that is what Lenora has been doing in the meantime for some of the NHLBI overseen ACTIV work.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 Mobile: [REDACTED] b6

From: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] b6 >
Sent: Tuesday, September 1, 2020 1:30 PM
To: Adam, Stacey (FNIH) [T] [REDACTED] b6 >
Cc: Culp, Michelle (NIH/OD) [E] [REDACTED] b6 ; Johnson, Lenora (NIH/NHLBI) [E] < [REDACTED] b6 >
Subject: RE: Follow-up on Prioritization within CT.gov

Hi Stacey,

I think you could start with Becky (Elizabeth) Williams at NLM. But first I think folks need to develop specific examples of searches that don't pull up the ACTIV trials high enough. I tried some searches, and got the results below (see 3 cases). I see that lots of other things are named ACTIV. Maybe one strategy is to ask the ICs to increase the # of uses of "ACTIV" in the actual entries, rather than just expecting CT.gov searches to change. And think about your starting point—NIH and FNIH webpages that have direct links to all of the ACTIV trials in CT.gov may be the safest bet, and/or instructions on what terms to use where in the CT gov search fields Or you could ask NLM to highlight the ACTIV trials with a direct link from the box about COVID:

3201 Studies found for **COVID-19**

Searched for **COVID** and **SARS-CoV-2** [See Search Details](#)

Your search included **COVID-19**

[Learn more about clinical studies related to COVID-19](#)

- [ClinicalTrials.gov](#) Federally-funded clinical studies related to COVID-19
- [WHO Trial Registry Network](#) COVID-19 studies from the [ICRP](#) database
- [NIH COVID-19 Treatment Guidelines](#)
- [ClinicalTrials.gov](#) [Views of Listed COVID-19 Studies \(Beta\)](#)

Anyway, take a look at this and let me know how you want to proceed. I am happy to do an introduct on to Becky if you want, or Michelle could ask for a recommendation.

Case 1: When I search for "ACTIV2) in the Other terms box (see below), I only get the ACTIV-2 Lily trial, so that works fine. Note that the entry specifically lists ACTIV-2 in the name of the drug: "Experimental: **ACTIV-2** Drug." I wonder if the other trials would come up higher if they used the ACTIV term in more places.

Find a study (all fields optional)

Status

- ☐ Recruiting and not yet recruiting studies
- ☐ All studies

Condition or disease For example: Depression

X

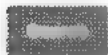
Other terms

ACTIV-2

X

Country

X



[Advanced Search](#)

Case 2: If I just search for "ACTIV" in "Other terms," the first page of results are other things (most of which have some variation of ACTIV in the title--see below). Unfortunately a lot of other things appear to use ACTIV so I am not sure how much clinicaltrials.gov can help with that.

Find a study (all fields optional)

Status

- ☐ Recruiting and not yet recruiting studies
- ☐ All studies

Condition or disease

X

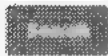
Other terms

ACTIV

X

Country

X



[Advanced Search](#)

Row	Saved	Status	Study Title	Conditions	Interventions
1	<input checked="" type="checkbox"/>	Pending	Randomized Trial Comparing Provera and Activ A.C. System to Conventional Care After Borealis Metastatic Surgery	<ul style="list-style-type: none"> Prioritised Disease 	<ul style="list-style-type: none"> Device: Provera™ eg ACTIV A.C.™ Therapy System
2	<input type="checkbox"/>	Completed	Evaluating a Behavioral Activities Treatment Program for Depressed Nursing Home Residents	<ul style="list-style-type: none"> Depression 	<ul style="list-style-type: none"> Behavioral: BE-ACTIV Behavioral: Treatment as usual (TAU)
3	<input checked="" type="checkbox"/>	Terminated too early	Activ A.C.® Compression Therapy Versus Compression Therapy Alone for the Treatment of Chronic Venous Ulcers	<ul style="list-style-type: none"> Chronic Venous Hypertension With Ulcer 	<ul style="list-style-type: none"> Device: ActivAC System Other: Compression therapy
4	<input type="checkbox"/>	Terminated	Efficacy of Exercise and Counseling Intervention on Relapse in Smokers With Depressive Disorders	<ul style="list-style-type: none"> Smoking Cessation Depression 	<ul style="list-style-type: none"> Behavioral: Exercise and counseling for smoker and physical activity)
5	<input type="checkbox"/>	Refused	Analysis of Chronic Non-Infectious Diseases Dynamics After COVID-19 Infection in Adult Patients	<ul style="list-style-type: none"> Covid19 SARS-CoV-2 Infection Pneumonia and 8 more... 	<ul style="list-style-type: none"> Other: non-interventional
6	<input checked="" type="checkbox"/>	Completed	Activ L™ Artificial Disc Treatment of Degenerative Disc Disease in the Treatment of Degenerative Disc Disease	<ul style="list-style-type: none"> Degenerative Disc Disease 	<ul style="list-style-type: none"> Device: Activ L Artificial Disc Device: ProDisc-L Total Disc Replacement or C Disc
7	<input type="checkbox"/>	Completed	The Neuropsychology of Approach-Avoidance in Treatment of Depression	<ul style="list-style-type: none"> Major Depressive Disorder 	<ul style="list-style-type: none"> Behavioral: Approach-positive AAT Behavioral: Control AAT
8	<input checked="" type="checkbox"/>	Completed	Cervical Spine Motor and Electromyography and Anterior Cervical Dissection in Cervical Spondylosis	<ul style="list-style-type: none"> Dissectomy Intervertebral Disk Displacement 	<ul style="list-style-type: none"> Device: Activ C disc prosthesis Procedure: Anterior cervical discectomy
9	<input checked="" type="checkbox"/>	Completed	Efficacy and Safety of Valeriana Among HIV Infection Patients	<ul style="list-style-type: none"> HIV infections Tobacco Dependence 	<ul style="list-style-type: none"> Drug: Valeriana Drug: Placebo
10	<input type="checkbox"/>	Unknown	ACTIV: Exercise Intervention in Healthy Young Men	<ul style="list-style-type: none"> Insulin Resistance 	<ul style="list-style-type: none"> Behavioral: Exercise

Case 3: Searching for "COVID" under Condition AND "ACTIV" under "Other terms" is better, although not perfect (and it looks like there is an ACTIV network in France doing COVID research). That makes me think that direct links to the specific CT.gov entries might be the best bet.

From: Adam, Stacey (FNIH) [T] b6
Sent: Tuesday, September 1, 2020 12:38 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6 >; Johnson, Lenora (NIH/NHLBI) [E] < b6
Subject: Follow-up on Prioritization within CT.gov

Hi Ellen,

I wanted to follow up on our conversation on Monday about reaching out to the NLM to determine if there is any ability to prioritize trials within CT.gov based on search terms. I would really appreciate if you would be able to put both myself and Lenora Johnson, cc'd here, in touch with the correct contacts, or if you would prefer to speak with NLM, and then follow up with us that would be good also. Would this be something you could assist us with at this time?

Also, if we don't feel we have a good contact at NLM, Lenora thought the lead comms person at CIT, Dan Luxenberg, might be a good start.

Please let me know if it would be good to discuss further before we approach anyone on our specific ask for the ACTIV master protocols in CT.gov.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 9/1/2020 5:35:43 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Johnson, Lenora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=059e53e386aa42fea27c7e17a4cc3cd7-johnslen]
Subject: RE: Follow-up on Prioritization within CT.gov

Got it.

From: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Sent: Tuesday, September 1, 2020 1:30 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Johnson, Lenora (NIH/NHLBI) [E] <[REDACTED]> **b6**
Subject: RE: Follow-up on Prioritization within CT.gov

Hi Michelle,

I appreciate the interjection. Just for context. We are simply looking for how we can get the ACTIV trials to come up at the top of the list when ACTIV is the search term in CT.gov.

Right now this is not the case.

Also, not all trials are obviously referenced at ACTIV, so we may need to make some amendments and knowing CT.gov parameters would be helpful.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [REDACTED] **b6** | Mobile: [REDACTED] **b6**

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] **b6**
Sent: Tuesday, September 1, 2020 1:27 PM
To: Culp, Michelle (NIH/OD) [E] [REDACTED] **b6** Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Cc: Johnson, Lenora (NIH/NHLBI) [E] [REDACTED] **b6**
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Thanks, Michelle. I am going to respond separately as I have done some searches and copied results into that email. Asking Patti sounds fine to me. I was going to suggest Becky Williams. Anyway, I'll send that now.

From: Culp, Michelle (NIH/OD) [E] [REDACTED] **b6** >
Sent: Tuesday, September 1, 2020 1:25 PM
To: Adam, Stacey (FNIH) [T] [REDACTED] **b6** . Gadbois, Ellen (NIH/OD) [E] [REDACTED] **b6** >

Cc: Johnson, Lenora (NIH/NHLBI) [E] b6
Subject: RE: Follow-up on Prioritization within CT.gov

Stacey and Ellen,

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Yesterday I spoke with the TransCelerate folks about the ACTIV master protocols and data sharing. They would like to learn more about data sharing agreements for master protocols (multiple sponsors).

Back in June, when I inquired about ACTIV patient level data sharing, it sounded like it would be challenging, given where things were in development. It sounds like this has changed.

-Michelle

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Sent: Tuesday, September 1, 2020 12:38 PM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >; Johnson, Lenora (NIH/NHLBI) [E] < b6 >
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Director, Cancer

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Sent: 9/1/2020 5:30:42 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: Follow-up on Prioritization within CT.gov

OK Heather and Nick Ide have been working with Gates Workbench (Steve Kern). They may have filled in while b6

From: Gadbois, Ellen (NIH/OD) [E] < b6 >
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Cc: Johnson, Lenora (NIH/NHLBI) [E] < b6 >
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Cc: Johnson, Lenora (NIH/NHLBI) [E] < b6 >
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 8/21/2020 3:57:45 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV vaccine WG in the news...

Yeah, that's what I was thinking. Not something she'd bring up, but she wouldn't want to be blindsided.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Sent: Friday, August 21, 2020 11:56 AM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: ACTIV vaccine WG in the news...

I don't know. I thought we could send it when we're asked about updates...

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6
Sent: Friday, August 21, 2020 11:54 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: ACTIV vaccine WG in the news...

Is Carrie aware?

Newsweek also stated:

Redfield's comments came as Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, told Reuters he would resign if the Trump administration pressured the agency to approve a COVID vaccine before it has been proven to be safe and effective.

Maybe Peter was asked to confirm statements from WG members?

-Michelle

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Sent: Friday, August 21, 2020 10:36 AM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]> b6 >; Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> b6
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6 >; Brodd, Lauren (NIH/OD) [E] <[REDACTED]> b6 >; Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6
Subject: FW: ACTIV vaccine WG in the news...

FYI Newsweek indicates there were 3 sources for information from what transpired in a supposedly confidential ACTIV WG call...

From: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Sent: Friday, August 21, 2020 10:29 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6 >; Wholley, David (FNIH) [T] <[REDACTED]> b6 > Menetski, Joseph (FNIH) [T] <[REDACTED]> b6 >; Santos, Michael (FNIH) [T] <[REDACTED]> b6
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6 >
Subject: RE: ACTIV vaccine WG in the news...

Less than optimal that things are still getting leaked from the WGs. Do we need to reaffirm to our teams that the info is not to be shared?

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b6) | Mobile: (b6)

From: Gadbois, Ellen (NIH/OD) [E] (b6) >

Sent: Friday, August 21, 2020 10:14 AM

To: Wholley, David (FNIH) [T] (b6) >; Menetski, Joseph (FNIH) [T] (b6) >; Santos, Michael (FNIH) [T] (b6) >; Adam, Stacey (FNIH) [T] (b6)

Cc: Culp, Michelle (NIH/OD) [E] (b6) />

Subject: ACTIV vaccine WG in the news...

<https://www.newsweek.com/cdc-director-hopeful-pandemic-will-end-spring-1526710>

During the conference call, some participants raised concerns that the administration could make a surprise announcement in October in a rush to unveil a vaccine before the elections. This is when Marks said he would resign if the FDA came under any political pressure to approve a vaccine that was not ready.

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy

Office of Science Policy

Office of the Director

National Institutes of Health

Building 1 Suite 218

voice: (b6)

fax: 301-402-0280



National Institutes of Health
Turning Discovery Into Health

From: Paul Frohna [REDACTED] b6
Sent: 8/14/2020 10:35:16 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Rashid, Kamilah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce52e57bb74034834aa8660b5c8677-rashidkl]; Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2bf13-walsher]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [REDACTED] b6
Subject: Re: confidentiality question re. NIH COVID-19 Portal Submission

Hi Stacey and thanks Ellen,
Thank you for that explanation of the process, it was very helpful and addressed my concerns.
I am looking forward to moving to the next step of the evaluation process through FNIH.
Best,
Paul

Paul A. Frohna, MD, PhD
Chief Medical Officer
ImCheck Therapeutics

On 14 Aug 2020, at 21:38, Adam, Stacey (FNIH) [T] <[REDACTED] b6> wrote:

Dear Dr. Frohna,

For submissions to the [ACTIV COVID-19 Clinical and Preclinical Candidate Compound Portal](#), which is the next step after you have expressed interest to the NIH via the original COVID-19 portal, for having your agent considered for use within an ACTIV trial, we allow you to submit the minimum data you are comfortable with for the initial review. Then, if the committee who are under confidentiality wish to see further information, we have your company complete a CDA with FNIH that has equal binding measures and flow through to the confidentiality agreements with the review team. Once that is complete, we then have you send the confidential data that you did not send in the first submission.

Below are couple of notes on the portal submission:

Please note that submission of a form is entirely voluntary and does not represent any kind of promise or commitment to consider for funding or actually provide funding for an agent or any activities associated with its development on the part of NIH or any of the ACTIV partners.

Also, while we have tried to limit the amount of data requested to those key elements that are necessary for practical scientific evaluation of agents for further development, the level of detail required to do so is not trivial. Because of this, the form may take 1-2 hours to complete,

depending on how much data a respondent has near to hand. For this reason the form has been designed so that it may be completed in stages, with a feature that allows users to save any partial data they have entered, quit and return to the survey at their convenience.

Please let us know if you have any further questions or if this will address your concerns.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 | Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] < b6 >

Sent: Friday, August 14, 2020 2:38 PM

To: Paul Frohna < b6 >

Cc: Rashid, Kamilah (NIH/OD) [E] < b6 > Walsh, Elizabeth (NIH/OD) [E]
< b6 > Adam, Stacey (FNIH) [T] < b6 > Parker, Ashley (NIH/OD) [E]
< b6 >

Subject: confidentiality question re. NIH COVID-19 Portal Submission

Dear Dr. Frohna,

Thanks for your interest in possible consideration of your therapeutic product by the ACTIV partnership. I am copying Dr. Stacey Adam at the Foundation for the NIH (FNIH), who can provide more specific information on the process of consideration by the ACTIV partners and the confidentiality measures. Stacey—Dr. Frohna had previously submitted information to the [NIH COVID-19 Candidates and Technology Portal](#) and is currently considering whether to consent to broader sharing of the information.

Best,
Ellen Gadbois

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy

Office of Science Policy

Office of the Director

National Institutes of Health

Building 1 Suite 218

voice: b6

fax: 301-402-0280

<image001.png>

From: Paul Frohna b6
Sent: Friday, August 14, 2020 12:42 PM
To: Walsh, Elizabeth (NIH/OD) [E] <el> b6
Cc: Rashid, Kamilah (NIH/OD) [E] b6 >; Gadbois, Ellen (NIH/OD) [E] b6 >
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Thanks Beth! Enjoyed speaking with you both today too.

Hi Ellen,
I spoke with Kamilah and Beth today about the ACTIV process as our submission as a potential therapeutic approach for COVID-19 was selected for the next step of evaluation at the FNIH, and was trying to understand the process and confidentiality measures during this process given that we are a small biotech where patents and confidentiality are important from a business standpoint. If you can provide any insight or contact info for the right person at FNIH, that would be greatly appreciated.
Thanks in advance,
Paul

Paul A. Frohna, MD, PhD
Chief Medical Officer

<image002.png>
31 Chemin Joseph Aiguier
13009 Marseille, France
Mob: + b6 (US) b6 (France)
Email : paul.frohna@imcheck.fr

From: Walsh, Elizabeth (NIH/OD) [E] b6 >
Sent: Friday, August 14, 2020 6:23 PM
To: Paul Frohna b6 >
Cc: Rashid, Kamilah (NIH/OD) [E] b6 >; Gadbois, Ellen (NIH/OD) [E] b6
Subject: Re: Please Respond by 8-20: NIH COVID-19 Portal Submission

Hi Paul,
It was a pleasure speaking with you this morning. I know you would like additional details about the ACTIV process and also how they handle confidentiality. Ellen Gadbois, cc'd here, has more insight into who the appropriate contact at FNIH is for your particular inquiries.

Best,
Beth

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/14/2020 6:42:49 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Rashid, Kamilah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce52e57bb74034834aa8660b5c8677-rashidkl]; Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2bf13-walsher]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: confidentiality question re. NIH COVID-19 Portal Submission

Thanks, Ellen,

I will keep you all copied.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b6), Mobile (b6)

From: Gadbois, Ellen (NIH/OD) [E] <(b6)>
Sent: Friday, August 14, 2020 2:40 PM
To: Adam, Stacey (FNIH) [T] <(b6)>
Cc: Rashid, Kamilah (NIH/OD) [E] <(b6)>; Walsh, Elizabeth (NIH/OD) [E] <(b6)>; Parker, Ashley (NIH/OD) [E] <(b6)>
Subject: RE: confidentiality question re. NIH COVID-19 Portal Submission

Stacey—dropping Paul. If you can copy us on your reply, we can use that for similar future questions so you don't need to field them (unless you would prefer to).

Thanks much,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Friday, August 14, 2020 2:38 PM
To: Paul Frohna (b6)
Cc: Rashid, Kamilah (NIH/OD) [E] (b6); Walsh, Elizabeth (NIH/OD) [E] (b6); Adam, Stacey (FNIH) [T] (b6); Parker, Ashley (NIH/OD) [E] <(b6)>
Subject: confidentiality question re. NIH COVID-19 Portal Submission

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Ellen Gadbois

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280



From: Paul Frohna b6
Sent: Friday, August 14, 2020 12:42 PM
To: Walsh, Elizabeth (NIH/OD) [E] < b6 >
Cc: Rashid, Kamilah (NIH/OD) [E] b6 Gadbois, Ellen (NIH/OD) [E] b6
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Thanks Beth! Enjoyed speaking with you both today too.

Hi Ellen,
I spoke with Kamilah and Beth today about the ACTIV process as our submission as a potential therapeutic approach for COVID-19 was selected for the next step of evaluation at the FNIH, and was trying to understand the process and confidentiality measures during this process given that we are a small biotech where patents and confidentiality are important from a business standpoint.
If you can provide any insight or contact info for the right person at FNIH, that would be greatly appreciated.
Thanks In advance,
Paul

Paul A. Frohna, MD, PhD
Chief Medical Officer



31 Chemin Joseph Aiguier
13009 Marseille, France
Mob: + b6 (US) b6 (France)
Email b6

From: Walsh, Elizabeth (NIH/OD) [E] b6
Sent: Friday, August 14, 2020 6:23 PM
To: Paul Frohna b6
Cc: Rashid, Kamilah (NIH/OD) [E] b6 ; Gadbois, Ellen (NIH/OD) [E] < b6
Subject: Re: Please Respond by 8-20: NIH COVID-19 Portal Submission

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Best,
Beth

From: Laurie Sower [REDACTED] b6
Sent: 9/9/2020 2:01:26 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Darrell Carney [REDACTED] b6 Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2fbf13-walsher]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Good morning all. I just wanted to follow up to see if there are other items that you may require for review. Can you also let us know the status of this submission.

Regards,
Laurie

From: Adam, Stacey (FNIH) [T] <[REDACTED] b6>
Sent: Wednesday, August 19, 2020 12:38 PM
To: Laurie Sower <[REDACTED] b6> Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6>
Cc: Darrell Carney <[REDACTED] b6> Walsh, Elizabeth (NIH/OD) [E] <[REDACTED] b6> Chen, Helen Q. <[REDACTED] b6>
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Thank you, Laurie, for your submission.

Best,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Laurie Sower <[REDACTED] b6>
Sent: Wednesday, August 19, 2020 1:35 PM
To: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6 >
Cc: Darrell Carney [REDACTED] b6 >; Walsh, Elizabeth (NIH/OD) [E] <[REDACTED] b6> Adam, Stacey (FNIH) [T] [REDACTED] b6 Chen, Helen Q. [REDACTED] b6 >
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Ellen
Thank you so much for your quick response. Please find the figure attached.

Best regards,

Laurie

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, August 19, 2020 11:57 AM
To: Laurie Sower <[REDACTED]> **b6**
Cc: Darrell Carney <[REDACTED]> **b6**; Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> **b6**; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**; Chen, Helen Q. <[REDACTED]> **b6**
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Dear Ms. Sower,
Can you please forward the graph to Stacey Adam and Helen Chen, cc'd here? They will insure that it is in REDCap.
Thanks,
Ellen Gadbois

From: Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, August 19, 2020 11:20 AM
To: Laurie Sower <[REDACTED]> **b6**
Cc: Darrell Carney <[REDACTED]> **b6**; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: Please Respond by 8-20: NIH COVID-19 Portal Submission

Hi Laurie,
We in the Office of the Director do not have access to the REDCap survey database to check whether your information rendered properly. That system is owned by another institute at NIH, NCATS. I'm connecting you here with Ellen Gadbois, cc'd here, from the Office of Science Policy who can direct you to the appropriate POC to find out if the submission by Dr. Carney looks OK.

Best,
Beth

From: Laurie Sower <[REDACTED]> **b6**
Date: Wednesday, August 19, 2020 at 9:46 AM
To: "Schwetz, Tara (NIH/OD) [E]" <[REDACTED]> **b6**; "Martin, Ann (NIH/OD) [E]" <[REDACTED]> **b6**; "Walsh, Elizabeth (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: Darrell Carney <[REDACTED]> **b6**
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Tara:
Good morning. We submitted the survey yesterday and we noted that the Graph of the dose dependency was not in the attached document. We did upload the graph and wanted to be sure that you all can see it on your side. If not, please let me know how to correct this issue.

Thank you in advance,
Laurie

From: Schwetz, Tara (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, August 5, 2020 12:24 PM
To: Laurie Sower <[REDACTED]> **b6**; Martin, Ann (NIH/OD) [E] <[REDACTED]> **b6**; Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Darrell Carney <[REDACTED]> **b6**
Subject: Re: Please Respond by 8-20: NIH COVID-19 Portal Submission

That should be fine. Thank you.

Best,

Tara A. Schwetz, PhD

Associate Deputy Director, NIH

Acting Director, NINR

A: Building 1, Room 138

P: **b6** | M: **b6**



From: Laurie Sower < **b6** >

Date: Wednesday, August 5, 2020 at 12:14 PM

To: Tara Schwetz **b6** , "Martin, Ann (NIH/OD) [E]" **b6** , "Walsh, Elizabeth (NIH/OD) [E]" **b6**

Cc: Darrell Carney < **b6** >

Subject: FW: Please Respond by 8-20: NIH COVID-19 Portal Submission

Tara,

Good morning! **b6** and he forwarded this email to me to sign on Chrysalis's behalf.

Is this acceptable to you?

Regards,

Laurie E. Sower, PhD

Executive Vice President

Chrysalis BioTherapeutics, Inc

2200 Market Street, Suite 609

Galveston, TX 77550

(M): **b6**

(O): **b6**

From: "Schwetz, Tara (NIH/OD) [E]" **b6**

Date: Wednesday, August 5, 2020 at 7:06 AM

To: "Darrell H. Carney" **b6**

Cc: "Martin, Ann (NIH/OD) [E]" **b6** , "Walsh, Elizabeth (NIH/OD) [E]"

< **b6** >

Subject: Please Respond by 8-20: NIH COVID-19 Portal Submission

Dear Dr. Carney,

I am writing to inform you that the National Institutes of Health (NIH) believes the information you submitted via the COVID-19 Candidates and Technology Portal (referred to as "the Portal" below) at <https://grants.nih.gov/grants/rfwr/rf.cfm?ID=107> may be of potential interest to NIH programs coordinating the response to COVID-19, including the Accelerated COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership.

NIH asks that you respond to the attached formal letter providing consent to use the contents of your Portal submission at the agency's discretion by August 20, 2020. This includes sharing your Portal submission, including any proprietary, confidential, or trade secret information therein, with other

GADB0000002661

parties, including but not limited to NIH's Federal, non-profit, industry, and international partners, and releasing such information to the general public. If you do not provide your consent, your Portal submission will not be considered for inclusion by ACTIV.

Thank you for your attention to this matter. If you have further questions about this matter, please contact me (**b6**)

Best,

Tara A. Schwetz, PhD

Associate Deputy Director

National Institutes of Health

Acting Director

National Institute of Nursing Research

A: 1 Center Drive, Room 138, Bethesda, MD 20892

P: **b6** | M: **b6**

E: **b6**



National Institutes of Health

Office of the Director

Disclaimer: The information in this email and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the originally intended recipient. If you have received this email in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institutes of Health (NIH) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of NIH by one of its representatives.

From: Walsh, Elizabeth (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F182B2C69FC94C0E813B762A8F2FBF13-WALSHER]
Sent: 8/19/2020 5:02:48 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: Re: Please Respond by 8-20: NIH COVID-19 Portal Submission

Thanks, Ellen!

From: "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Wednesday, August 19, 2020 at 12:57 PM
To: Laurie Sower <[REDACTED]> **b6**
Cc: Darrell Carney <[REDACTED]> **b6**; "Walsh, Elizabeth (NIH/OD) [E]" <[REDACTED]> **b6**
"Adam, Stacey (FNIH) [T]" <[REDACTED]> **b6**; "Chen, Helen Q." <[REDACTED]> **b6**
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Cc: Darrell Carney <[REDACTED]> **b6**; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
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Cc: Darrell Carney <[REDACTED]> **b6**
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Subject: Re: Please Respond by 8-20: NIH COVID-19 Portal Submission

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Associate Deputy Director, NIH
Acting Director, NINR
A: Building 1, Room 138
P: b6 | M: b6



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Date: Wednesday, August 5, 2020 at 12:14 PM
To: Tara Schwetz < b6 > "Martin, Ann (NIH/OD) [E]" b6 >, "Walsh, Elizabeth (NIH/OD) [E]" b6
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Is this acceptable to you?

Regards,
Laurie E. Sower, PhD
Executive Vice President
Chrysalis BioTherapeutics, Inc
2200 Market Street, Suite 609
Galveston, TX 77550
(M): b6
(O): b6

From: "Schwetz, Tara (NIH/OD) [E]" b6
Date: Wednesday, August 5, 2020 at 7:06 AM
To: "Darrell H. Carney" b6
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Associate Deputy Director

National Institutes of Health

Acting Director

National Institute of Nursing Research

A: 1 Center Drive, Room 138, Bethesda, MD 20892

P: b6 | M: b6

E: b6



National Institutes of Health

Office of the Director

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Sent: 7/14/2020 5:04:35 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Invitation Language for Compound Survey

Hi Ellen,

I think if you start at June 13th you should be covered.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b6) Mobile: (b6)

From: Gadbois, Ellen (NIH/OD) [E] <(b6)>
Sent: Tuesday, July 14, 2020 1:00 PM
To: Adam, Stacey (FNIH) [T] <(b6)>
Cc: Menetski, Joseph (FNIH) [T] <(b6)>
Subject: RE: Invitation Language for Compound Survey

Great. Do you know when was the last date Ashley sent you names of companies/investigators that you did invite to fill out the survey? I'll ask Ashley to create a list that starts after that date and give to NCATS.

From: Adam, Stacey (FNIH) [T] (b6)
Sent: Tuesday, July 14, 2020 12:55 PM
To: Gadbois, Ellen (NIH/OD) [E] (b6)
Cc: Menetski, Joseph (FNIH) [T] (b6) >
Subject: RE: Invitation Language for Compound Survey

Hi Ellen,

Basically whatever Ashley sent that was marked clinical or preclinical.

Thanks,
stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct (b6) Mobile: (b6)

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6 >
Sent: Tuesday, July 14, 2020 12:54 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Cc: Menetski, Joseph (FNIH) [T] [REDACTED] b6
Subject: RE: Invitation Language for Compound Survey

Thanks. Is the list basically whatever Ashley sent you, or had you trimmed it down?

From: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Sent: Tuesday, July 14, 2020 12:48 PM
To: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Cc: Menetski, Joseph (FNIH) [T] [REDACTED] b6
Subject: Invitation Language for Compound Survey

Hi Ellen,

Below is the language that we have been using. We have not reached out to anyone since June 16th, so anything vetted for ACTIV after that, that is preclinical or clinical would need to receive this invitation. I can't send you the list because apologies I deleted it before thinking to send it to you.

Thanks,
Stacey

Dear Investigators and Colleagues,

We want to reach out and remind you to complete the [ACTIV COVID-19 Clinical and Preclinical Candidate Compound Survey](#), if you are interested and have a therapeutic candidate that could be promising enough for inclusion in future ACTIV or NIH trial protocols. The ACTIV team is in the process of agent prioritization, and complete submissions by **EOD (ET) on July 14** will be included in our next round of evaluation.

Please note that submission of a form is entirely voluntary and does not represent any kind of promise or commitment to consider for funding or actually provide funding for an agent or any activities associated with its development on the part of NIH or any of the ACTIV partners.

Please note that while we have tried to limit the amount of data requested to those key elements that are necessary for practical scientific evaluation of agents for further development, the level of detail required to do so is not trivial. Because of this, the form may take 1-2 hours to complete, depending on how much data a respondent has near to hand. For this reason the form has been designed so that it may be completed in stages, with a feature that allows users to save any partial data they have entered, quit and return to the survey at their convenience.

We welcome submissions from stakeholders throughout the biopharmaceutical, academic, scientific research, advocacy, clinical practice communities, and the general public. Please feel free to share this with your colleagues who may have promising agents for ACTIV to consider.

Thank you!

Kind regards,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: **b6** Mobile: **b6**

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/19/2020 4:55:03 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]
CC: Walsh, Elizabeth (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f182b2c69fc94c0e813b762a8f2bf13-walsher]; Chen, Helen Q [REDACTED]
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Hi Ellen,

You can have her forward it directly to Helen and I with a copy of their pdf of their completed survey. We can then ensure that we have both.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [REDACTED], Mobile [REDACTED]

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, August 19, 2020 12:12 PM
To: Jonson, Samantha (NIH/NCATS) [E] <[REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED]>
Cc: Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]>
Subject: FW: Please Respond by 8-20: NIH COVID-19 Portal Submission

Hi Sam & Stacey,

We have a question from Laurie Sower at Chrysbio about whether their graph of dose dependency for their therapeutic candidate, Chrysalin, got uploaded properly into REDCap. Can you let me know if it is there or if there's other guidance to give Ms. Sower?

Thanks,
Ellen

From: Walsh, Elizabeth (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, August 19, 2020 11:20 AM
To: Laurie Sower <[REDACTED]>
Cc: Darrell Carney <[REDACTED]> Gadbois, Ellen (NIH/OD) [E] <[REDACTED]>
Subject: Re: Please Respond by 8-20: NIH COVID-19 Portal Submission

Hi Laurie,

We in the Office of the Director do not have access to the REDCap survey database to check whether your information rendered properly. That system is owned by another institute at NIH, NCATS. I'm connecting you here with Ellen Gadbois, cc'd here, from the Office of Science Policy who can direct you to the appropriate POC to find out if the submission by Dr. Carney looks OK.

Best,
Beth

From: Laurie Sower <[REDACTED] b6>
Date: Wednesday, August 19, 2020 at 9:46 AM
To: "Schwetz, Tara (NIH/OD) [E]" [REDACTED] b6 >, "Martin, Ann (NIH/OD) [E]" [REDACTED] b6
"Walsh, Elizabeth (NIH/OD) [E]" [REDACTED] b6
Cc: Darrell Carney [REDACTED] b6 >
Subject: RE: Please Respond by 8-20: NIH COVID-19 Portal Submission

Tara:
Good morning. We submitted the survey yesterday and we noted that the Graph of the dose dependency was not in the attached document. We did upload the graph and wanted to be sure that you all can see it on your side. If not, please let me know how to correct this issue.

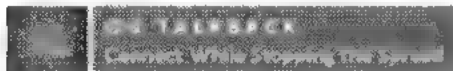
Thank you in advance,
Laurie

From: Schwetz, Tara (NIH/OD) [E] <[REDACTED] b6>
Sent: Wednesday, August 5, 2020 12:24 PM
To: Laurie Sower [REDACTED] b6; Martin, Ann (NIH/OD) [E] [REDACTED] b6 >; Walsh, Elizabeth (NIH/OD) [E] <eliza[REDACTED] b6>
Cc: Darrell Carney [REDACTED] b6
Subject: Re: Please Respond by 8-20: NIH COVID-19 Portal Submission

That should be fine. Thank you.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
Acting Director, NINR
A: Building 1, Room 138
P: 301-402-3965 | M: 301-538-4920



From: Laurie Sower [REDACTED] b6
Date: Wednesday, August 5, 2020 at 12:14 PM
To: Tara Schwetz <[REDACTED] b6> "Martin, Ann (NIH/OD) [E]" <an[REDACTED] b6> "Walsh, Elizabeth (NIH/OD) [E]" <el[REDACTED] b6>
Cc: Darrell Carney <[REDACTED] b6>
Subject: FW: Please Respond by 8-20: NIH COVID-19 Portal Submission

Tara:
Good morning! [REDACTED] b6 and he forwarded this email to me to sign on Chrysalis's behalf. Is this acceptable to you?

Regards,

Laurie E. Sower, PhD
Executive Vice President
Chrysalis BioTherapeutics, Inc
2200 Market Street, Suite 609
Galveston, TX 77550
(M): [REDACTED] b6
(O): [REDACTED] b6

From: "Schwetz, Tara (NIH/OD) [E]" b6
Date: Wednesday, August 5, 2020 at 7:06 AM
To: "Darrell H. Carney" b6
Cc: "Martin, Ann (NIH/OD) [E]" b6 >, "Walsh, Elizabeth (NIH/OD) [E]" b6 >
Subject: Please Respond by 8-20: NIH COVID-19 Portal Submission

Dear Dr. Carney,

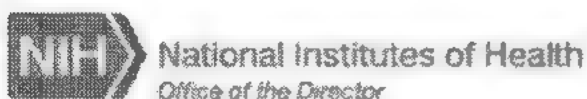
I am writing to inform you that the National Institutes of Health (NIH) believes the information you submitted via the COVID-19 Candidates and Technology Portal (referred to as "the Portal" below) at <https://grants.nih.gov/grants/rfi/rfi.cfm?ID=107> may be of potential interest to NIH programs coordinating the response to COVID-19, including the Accelerated COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership.

NIH asks that you respond to the attached formal letter providing consent to use the contents of your Portal submission at the agency's discretion by August 20, 2020. This includes sharing your Portal submission, including any proprietary, confidential, or trade secret information therein, with other parties, including but not limited to NIH's Federal, non-profit, industry, and international partners, and releasing such information to the general public. If you do not provide your consent, your Portal submission will not be considered for inclusion by ACTIV.

Thank you for your attention to this matter. If you have further questions about this matter, please contact me ([REDACTED] b6)

Best,

Tara A. Schwetz, PhD
Associate Deputy Director
National Institutes of Health
Acting Director
National Institute of Nursing Research
A: 1 Center Drive, Room 138, Bethesda, MD 20892
P: [REDACTED] b6 | M: [REDACTED] b6
E: [REDACTED] b6



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n error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institutes of Health (NIH) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of NIH by one of its representatives.

From: Young, Cari (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7765319E02C347ED8466C56E5AE61BE5-YOUNGCE]
Sent: 9/3/2020 1:55:56 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

I can't think of anything that we're active enough in the AI arena that we could provide source material on, so I agree that I don't think we have anything to supply there. I am less involved in COVID, so defer to others there, but I am not personally aware of anything we would want to supply.

From: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] b6 >
Sent: Thursday, September 3, 2020 9:43 AM
To: Tucker, Jessica (NIH/OD) [E] < [REDACTED] b6 >
Cc: Brodd, Lauren (NIH/OD) [E] < [REDACTED] b6 >; Young, Cari (NIH/OD) [E] < [REDACTED] b6 >
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

I'm confused. I think Tyrone needs to clarify who is supposed to write the narratives. We have opposing directions:

1. Sections of the CJ narrative have already been assigned to various groups. Lauren, Michelle, Ashley and I have the ACTIV section and created the outline. Yesterday Jessica Creery wrote asking that we finish the ACTIV narrative by Oct 23 (attached).
2. But at the bottom this current email chain, Erica Landis (IMOD) writes: "IMOD will be taking the first pass at writing the Narrative section, the source material you contribute will be used to inform the writing process. For topics to submit source material on, please refer to the blue text in the CJ outline which indicates which OD Offices have played a role in each topic."

So I don't know who is doing the writing. But if it's IMOD, then we had better identify all of the sources they might use. FYI I'm not sure how IMOD will write up AMP, since there's no longer a good source since the BRAIN topic got archived. There is stuff on the NIH website, but it's (intentionally) pretty general.

Jessica, do you want to take this up with Tyrone? Alternatively I can write to Jessica C since she just asked the ACTIV team to write that narrative.

From: Tucker, Jessica (NIH/OD) [E] < [REDACTED] b6 >
Sent: Thursday, September 3, 2020 9:11 AM
To: Gadbois, Ellen (NIH/OD) [E] < [REDACTED] b6 >
Cc: Brodd, Lauren (NIH/OD) [E] < [REDACTED] b6 >; Young, Cari (NIH/OD) [E] < [REDACTED] b6 >
Subject: Re: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Thanks. If the topic is not relevant to us, we just won't submit anything. I think Tyrone was just guessing what might be OSP-relevant.

From: "Gadbois, Ellen (NIH/OD) [E]" < [REDACTED] b6 >
Date: Thu, Sep 3, 2020, 8:49 AM

To: "Tucker, Jessica (NIH/OD) [E]" b6
CC: "Brodd, Lauren (NIH/OD) [E]" b6 >, "Young, Cari (NIH/OD) [E]" b6
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Got it. I will respond on AMP.

I am not sure who in OSP is dealing with the All of Us COVID testing, but that's not an ACTIV function. I don't know what All of Us is doing there.

I'm also not sure who is handling the BRAIN Initiative part, but presumably they will know to include the BNS report to the ACD as source material.

From: Tucker, Jessica (NIH/OD) [E] b6
Sent: Thursday, September 3, 2020 7:12 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Young, Cari (NIH/OD) [E] b6
Cc: Brodd, Lauren (NIH/OD) [E] < b6
Subject: FW: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Ellen and Cari (and ccing Lauren for awareness),

Looping you in re: AMP, COVID, and AI. I have not looked at this yet, but my guess is we would be unlikely to have anything for COVID or AI, but perhaps for AMP. Based on the subject line, I think Tyrone is looking for edits by 12 PM tomorrow.

Thanks,

Jessica

From: Spady, Tyrone (NIH/OD) [E] b6
Sent: Wednesday, September 2, 2020 7:00 PM
To: Bayha, Ryan (NIH/OD) [E] < b6 Berger, Adam (NIH/OD) [E] < b6 Diggs, Susan (NIH/OD) [E] < b6 />; Fennington, Kelly (NIH/OD) [E] b6 , Isaacman-Beck, Jesse (NIH/OD) [E] b6 Jorgenson, Lyric (NIH/OD) [E] < b6 Koniges, Ursula (NIH/OD) [E] < b6 >; Paine, Taunton (NIH/OD) [E] b6 ; Rohrbaugh, Mark (NIH/OD) [E] < b6 Tucker, Jessica (NIH/OD) [E] b6 >; Wolinetz, Carrie (NIH/OD) [E] b6 Gadbois, Ellen (NIH/OD) [E] b6
Cc: Creery, Jessica (NIH/OD) [E] b6 >
Subject: RE: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Hi all:

It looks like some of you might not have access to the Teams site. As work-arounds, I'm attaching the full OD CJ outline and please send your additions to me and Jessica Creery. We can upload for you.

Cheers,
T-

From: Spady, Tyrone (NIH/OD) [E] b6
Sent: Wednesday, September 2, 2020 5:47 PM
To: Bayha, Ryan (NIH/OD) [E] < b6 Berger, Adam (NIH/OD) [E] < b6 Diggs, Susan (NIH/OD) [E] < b6 />; Fennington, Kelly (NIH/OD) [E] b6 , Isaacman-Beck, Jesse

(NIH/OD) [E] < [REDACTED] b6 Jorgenson, Lyric (NIH/OD) [E] b6 Koniges, Ursula
(NIH/OD) [E] < [REDACTED] b6 >; Paine, Taunton (NIH/OD) [E] b6 Rohrbaugh, Mark
(NIH/OD) [E] < [REDACTED] b6 >; Spady, Tyrone (NIH/OD) [E] < [REDACTED] b6 Tucker, Jessica (NIH/OD)
[E] b6 >; Wolinetz, Carrie (NIH/OD) [E] b6 >; Gadbois, Ellen (NIH/OD) [E]

Cc: Creery, Jessica (NIH/OD) [E] < [REDACTED] b6

Subject: ACTION REQUESTED: Call for source material - OD CJ [Due 12p 9/4]

Hi all:

IMOD has issued a call for source material (reports, websites, formal announcements, etc...) for the OD Congressional Justification narrative (see below). Some of you may have already provided your contributions. If so, please let me know. We've listed the topics where OSP might have source materials to add. Please add any relevant source material on the subjects listed below (Full doc: [OD CJ Outline](#)) to the Teams folder named "Narrative Source Material" by COB on Friday, September 4th. Let me know if you have any questions.

OSP relevant subjects

1. **BRAIN Initiative updates**
2. **Accelerating Medicines Partnerships**
3. **NIH efforts on Data Science and Artificial Intelligence**
 1. **Data sharing policies**
 2. **Harnessing Data Science for Health Discovery and Innovation in Africa**
 3. **Artificial Intelligence for Biomedical Excellence (AIBLE) program**
 4. **Artificial Intelligence to address chronic disease**
 5. **Collaboration with NASEM on Behavioral Ontologies**
 6. **Updating MeSH terms**
4. **Rigor and Reproducibility**
 1. **ACD Working Group on Enhancing Reproducibility and Rigor in Animal Research**
5. **Program Portraits**
 1. All of Us COVID-19 Testing, highlighting the Electronic Health Record Data survey to provide researchers with easy to use data on how participants are experiencing COVID-19 while maintaining privacy
 2. **Strengthening Anti-Harassment Policies at NIH, updates from the ACD Working Group, implementation of new policies, and support for continued growth and development**
 3. Updating the NIH-wide Strategic Plan, a trans-NIH effort guided by the OD to outline the NIH vision for biomedical research, opportunities for scientific exploration, and address new challenges for the next five years.

Cheers,
Tyrone

From: Landis, Erica (NIH/OD) [E] [REDACTED] b6

Sent: Tuesday, September 1, 2020 5:09 PM

To: Culhane, Ned (NIH/OD) [E] [REDACTED] b6 Hentges, Justin (NIH/OD) [E] [REDACTED] b6 ;

Heath Mason, Matthew (NIH/OD) [E] [REDACTED] b6 Le Fauve, Charlene (NIH/OD) [E]

[REDACTED] b6 >; Kawazoe, Robin (NIH/OD) [E] < [REDACTED] b6 Spady, Tyrone (NIH/OD) [E]

< [REDACTED] b6 Creery, Jessica (NIH/OD) [E] < [REDACTED] b6 Noursi, Samia (NIH/OD) [E]

[REDACTED] b6 >; Morris, Patricia (NIH/NICHD) [E] [REDACTED] b6 Luetkemeier, Erin (NIH/OD) [E]

[REDACTED] b6 >; Klock, Kevin (FNIH) [T] < [REDACTED] b6 >; Edghill Spano, Yvette (NIH/OD) [E]

< [REDACTED] b6 Espinoza, Tasha (NIH/OD) [E] < [REDACTED] b6 >; Morris, Kathryn (NIH/OD) [E]

[REDACTED] b6 Myles, Renate (NIH/OD) [E] < [REDACTED] b6 Burklow, John (NIH/OD) [E]

[REDACTED] b6 >; Peterman Cross, Wilma (NIH/OD) [E] [REDACTED] b6 Thurn, Anne (NIH/OD) [E]

< [REDACTED] b6 Kosub, David (NIH/OD) [E] < [REDACTED] b6 Columbus, Megan (NIH/OD) [E]

[REDACTED] b6 >; Rabin, Elise (NIH/OD) [E] [REDACTED] b6 Owens, Roland (NIH/OD) [E]

b6 Murray, Darryl (NIH/OD) [E] < b6 Shorback, Janet (NIH/OD) [E]
Stevens, Mark (NIH/OD) [E] < b6 >; Newman, Patricia (NIH/OD) [E]
; Spencer, Elizabeth (NIH/OD) [E] b6 Ekweani, Elonna (NIH/OD) [E]
>; Vonkollmar, Desiree (NIH/OD) [E] b6 ; Courchesne, Stephanie (NIH/OD)
[E] b6 >; Fennington, Kelly (NIH/OD) [E] < b6 ; Spaniol, Erin (NIH/OD) [E]
< b6 Baker, Rebecca (NIH/OD) [E] < b6
Cc: Mazzucco, Anna (NIH/OD) [E] b6
Subject: Re: Request: Source material for OD CJ Narrative draft

Dear all,

Thank you to those who have already provided source material for the OD Congressional Justification narrative. If you have not had a chance to yet, please add any relevant source material on the subjects listed in the OD CJ Outline to the Teams folder named "Narrative Source Material" by COB on Friday, September 4th.

Please feel free to reach out with any questions you have.

Very best,
Erica

Erica G. Landis, PhD
AAAS Science & Technology Policy Fellow
Immediate Office of the Director
National Institutes of Health
A: Building 1, Room 114
P: b6

From: "Landis, Erica (NIH/OD) [E]" b6
Date: Monday, August 24, 2020 at 12:04 PM
To: "Cuihane, Ned (NIH/OD) [E]" b6 "Hentges, Justin (NIH/OD) [E]"
b6 "Heath-Mason, Matthew (NIH/OD) [E]" < b6 . "Le
Fauve, Charlene (NIH/OD) [E]" < b6 "Kawazoe, Robin (NIH/OD) [E]"
< b6 >, "Spady, Tyrone (NIH/OD) [E]" < b6 >, "Creery, Jessica (NIH/OD)
[E]" b6 "Noursi, Samia (NIH/OD) [E]" b6 >, "Morris, Patricia
(NIH/NICHD) [E]" b6 "Luetkemeier, Erin (NIH/OD) [E]" < b6
"Klock, Kevin (FNIH) [T]" b6 "Edghill Spano, Yvette (NIH/OD) [E]"
b6 >, "Espinoza, Tasha (NIH/OD) [E]" b6 . "Morris, Kathryn
(NIH/OD) [E]" b6 "Myles, Renate (NIH/OD) [E]" b6 , "Burklow,
John (NIH/OD) [E]" b6 >, "Peterman Cross, Wilma (NIH/OD) [E]"
< b6 "Thurn, Anne (NIH/OD) [E]" b6 >, "Kosub, David (NIH/OD) [E]"
< b6 "Columbus, Megan (NIH/OD) [E]" < b6 "Rabin, Elise (NIH/OD)
[E]" b6 , "Owens, Roland (NIH/OD) [E]" < b6 "Murray, Darryl (NIH/OD)
[E]" b6 >, "Shorback, Janet (NIH/OD) [E]" < b6 . "Stevens, Mark
(NIH/OD) [E]" b6 . "Newman, Patricia (NIH/OD) [E]" b6 ,
"Spencer, Elizabeth (NIH/OD) [E]" b6 , "Ekweani, Elonna (NIH/OD) [E]"
< b6 . "Vonkollmar, Desiree (NIH/OD) [E]" < b6 . "Courchesne,
Stephanie (NIH/OD) [E]" < b6 "Fennington, Kelly (NIH/OD) [E]"
<fenningk@od.nih.gov>, "Spaniol, Erin (NIH/OD) [E]" b6 , "Baker, Rebecca (NIH/OD) [E]"
< b6

Cc: Anna Mazzucco <[REDACTED]> b6

Subject: Request: Source material for OD CJ Narrative draft

Dear all,

Thank you for all of your help in developing the OD Congressional Justification outline. Please see below a request for our next step.

ASK: Please submit any relevant source material on the subjects listed in the OD CJ Outline to the Teams folder named "Narrative Source Material" **by COB on Friday, September 4th**.

Background and Process: We greatly appreciate your help in developing the OD Congressional Justification outline for FY22. As the FY22 CJ Outline moves through the OLPA review process, we would like to begin collecting source material for the CJ Narrative to support the initial drafting process. IMOD will be taking the first pass at writing the Narrative section, the source material you contribute will be used to inform the writing process. For topics to submit source material on, please refer to the blue text in the CJ outline which indicates which OD Offices have played a role in each topic. Source material can include previously written or new reports, press releases, analyses, or any other documents which describe the program or topic. Once the Narrative is drafted, we will distribute it to you for your review before submission to OLPA.

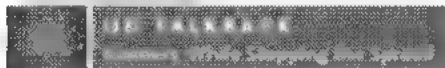
For a reminder on the timeline for the OD CJ, please refer to the Timeline tab in Teams.

Please let us know if you have any questions or concerns. We appreciate you taking the time to provide feedback. Thank you in advance for your input!

Much appreciation,
Erica

Erica G. Landis, PhD
AAAS Science & Technology Policy Fellow
Immediate Office of the Director
National Institutes of Health
A: Building 1, Room 114

P: [REDACTED] b6



From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 7/8/2020 8:21:45 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV consents and protocols

Oh, my!

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, July 8, 2020 2:56 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: ACTIV consents and protocols

Best to get it all hammered out up front, before enrollment. At least you are not chasing down already-shared information....

From: Culp, Michelle (NIH/OD) [E] [REDACTED] b6
Sent: Wednesday, July 8, 2020 12:45 PM
To: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Subject: FW: ACTIV consents and protocols

Ellen,
I'll mention this to Lyric and start drafting an email to Larry. I need clarity from Leadership on scope of data sharing: only ACTIV trials or all COVID studies? Summary data or individual patient level data? Access to ACTIV "members" or anyone under the sun?

-Michelle

From: Culp, Michelle (NIH/OD) [E]
Sent: Wednesday, July 8, 2020 12:41 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Cc: Wholley, David (FNIH) [T] [REDACTED] b6 >; Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Subject: RE: ACTIV consents and protocols

Stacey,
Thanks for the 2 draft consents. The ACTIV-2 (ACTG outpatient) consent is really well written.

- The ACTIV-2 consent does not make any statements about sharing the subjects data (patient level data) with anyone.
- The ACTIV-3 (inpatient) consent states subject data may be shared with other COVID19 researchers. "UMN may share your data and specimens with other people who study COVID-19. UMN will remove any information that could possibly be used to identify you before sharing. This is called "anonymizing the data." We will not ask you for additional consent for this sharing. UMN will only share data and specimens for research projects that are approved by the group that is conducting this study."

If ACTIV patient level data is going to be deposited into DataCelerate (or elsewhere) consent language will need to be amended.

A couple unsolicited comments that you can take or disregard:

- The ACTIV-3 consent on page 1 says the study is sponsored by UMN. Do they mean IND Sponsor?
- The ACTIV-3 consent allows pregnant women to enroll, but disallows pregnancy (women and their partners) during the trial. ACTIV-2 (using the same or similar products) does not prohibit pregnancy during the trial. This seems incongruous.

From: Adam, Stacey (FNIH) [T] b6
Sent: Tuesday, July 7, 2020 4:42 PM
To: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: ACTIV consents and protocols

Hi Michelle,

Here are the two for ACTIV-2 and ACTIV-3. ACTIV-1 is still working on theirs and I don't have access to ACTIV-4.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 | Mobile: b6

From: Culp, Michelle (NIH/OD) [E] b6 >
Sent: Tuesday, July 7, 2020 12:51 PM
To: Wholley, David (FNIH) [T] b6 >; Adam, Stacey (FNIH) [T] b6 >; Santos, Michael (FNIH) [T] <m b6
Cc: Gadbois, Ellen (NIH/OD) [E] < b6 Parker, Ashley (NIH/OD) [E] b6
Menetski, Joseph (FNIH) [T] b6
Subject: ACTIV consents and protocols

Dear David, Stacey and Mike,

I'm continuing my conversations with DataCelerate and Gates Workbench about sharing patient and summary level data. To move forward with sharing any ACTIV trial data, we need to know how this is written in the informed consent documents and protocols with regard to data sharing, privacy, data access and future use of data.

Would you be able to provide me the consents and protocols so we can review that text?

Thank you.
Best regards,
Michelle

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 6/25/2020 7:04:08 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: FW: Corporate Communications Contacts at Allergan/AbbVie and BMS

FYI

From: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Sent: Thursday, June 25, 2020 3:02 PM
To: Gorman, Greta (FNIH) [T] <[REDACTED]> **b6** Meltzer, Abbey (FNIH) [T] <[REDACTED]> **b6** Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** Chen, Helen Q. <[REDACTED]> **b6** Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: FW: Corporate Communications Contacts at Allergan/AbbVie and BMS

Hi Renate, Abbey, and Greta,

The companies that have agreed to participation in the ACTIV-1 master protocol would like to have a communications strategy session about when/how to communicate their participation in the trial.

They have provided the following times that they are able to meet. Would any of these work for the 3 of you?

- Monday: 2-3 PM CT/3-4pm ET
- Tuesday: 11 AM – 1 PM CT/12-2pm ET
- Wednesday: 11 AM – 2 PM CT/12-3pm ET

For more context and their emails, please see the email string below.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] **b6** Mobile: [REDACTED] **b6**

From: Moyo, Vusi <[REDACTED]> **b6**
Sent: Thursday, June 25, 2020 12:56 PM
To: Trank, Christina <[REDACTED]> **b6** >; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Cc: Beumont-Mauviel, Maria [JRDUS] <[REDACTED]> **b6** >
Subject: RE: Corporate Communications Contacts at Allergan/AbbVie and BMS

Hi Stacey,

The following times/dates work for me:

- Monday: 2-3 PM CT
- Tuesday: 11 AM – 1 PM CT

• Wednesday: 11 AM – 2 PM CT

Best,
Vusi

VUSI MOYO
Director
R&D Communications

abbvie

1 North Waukegan Rd.
North Chicago, IL 60064

CELL **b6**
EMAIL **b6**

abbvie.com

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From: Trank, Christina **b6**
Sent: Thursday, June 25, 2020 11:21 AM
To: Adam, Stacey (FNIH) [T] < **b6** >
Cc: Beumont-Mauviel, Maria [JRDUS] **b6** ; Moyo, Vusi **b6**
Subject: [EXTERNAL] RE: Corporate Communications Contacts at Allergan/AbbVie and BMS

Thanks Stacey – that makes sense. A call would be helpful to understand the NIH's plans for communications and timing.

I can likely make myself available any time before noon on Monday, and anytime Wednesday or Thursday.

Thank you,
Chrissy

From: Adam, Stacey (FNIH) [T] **b6**
Sent: Thursday, June 25, 2020 12:15 PM
To: Trank, Christina **b6**
Cc: Beumont-Mauviel, Maria [JRDUS] **b6** >; Moyo, Vusi **b6**
Subject: RE: Corporate Communications Contacts at Allergan/AbbVie and BMS

[Use CAUTION when opening links/attachments]

Dear Chrissy, Maria, and Vusi,

If you would like to try to meet, please suggest sometimes that I can suggest to Renate and a few others who would need to be in attendance.

I did want to let you know that we will not be able to make any official public announcements of your agents on the trial until after contracts are signed with the designated sponsor. However, I know this is not the only concern to plan for, so happy to speak further.

GADB0000003001

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 Mobile: [REDACTED] b6

From: Trank, Christina [REDACTED] b6
Sent: Thursday, June 25, 2020 8:57 AM
To: Adam, Stacey (FNIH) [T] [REDACTED] b6
Cc: Beumont-Mauviel, Maria [JRDUS] [REDACTED] b6 >; Moyo_Vusi [REDACTED] b6 >
Subject: RE: Corporate Communications Contacts at Allergan/AbbVie and BMS

Great to meet you all. Should we try to connect before the holiday?

Thanks,
Chrissy

Chrissy Trank
Director | Corporate Affairs
R&D Communications

Office + [REDACTED] b6
Mobile +1 [REDACTED] b6
[REDACTED] b6



From: Adam, Stacey (FNIH) [T] [REDACTED] b6 >
Sent: Monday, June 22, 2020 2:51 PM
To: Bharucha_David <b [REDACTED] b6 >; Sadeh, Jonathan [REDACTED] b6 >; Melsheimer, Rich [CNTNL] [REDACTED] b6 >; Gavin, Brian [REDACTED] b6 >
Cc: Beumont-Mauviel, Maria [JRDUS] [REDACTED] b6 >; Trank, Christina [REDACTED] b6 >; Moyo_Vusi [REDACTED] b6 >
Subject: RE: Corporate Communications Contacts at Allergan/AbbVie and BMS

[Use CAUTION when opening links/attachments]

Thanks, David,

I will make sure these contacts also get to the NIH Communications lead for ACTIV Renate Miles, so she knows who to coordinate with.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [REDACTED] b6 , Mobile: [REDACTED] b6

From: Bharucha_David [REDACTED] b6 >

Sent: Monday, June 22, 2020 1:40 PM

To: Melsheimer, Rich [CNTNL] [REDACTED] b6 >; Gavin, Brian [REDACTED] b6 >; Sadeh, Jonathan [REDACTED] b6

Cc: Beumont-Mauviel, Maria [JRDUS] [REDACTED] b6 >; Trank, Christina <[REDACTED] b6 >;

Moyo_Vusi [REDACTED] b6 Adam, Stacey (FNIH) [T] [REDACTED] b6 >

Subject: RE: Corporate Communications Contacts at Allergan/AbbVie and BMS

Dear colleagues,

I'm looping in **Vusi Moyo** (Director, R&D Communications, AbbVie) as the point-person for ACTIV-1 external communications from my stand-point. I'm also cc'ing Stacey for her awareness.

Thanks,

David

David B. Bharucha, MD, PhD, FACC
Vice President, Clinical Development, R&D

abbvie

5 Giralda Farms
Madison, NJ 07940

Office: + [REDACTED] b6

Cell: [REDACTED] b6

David.Bharucha@Allergan.com

From: Melsheimer, Rich [CNTNL] [REDACTED] b6 >

Sent: Monday, June 22, 2020 5:15 AM

To: Gavin, Brian [REDACTED] b6 >; Bharucha_David [REDACTED] b6 ; Sadeh, Jonathan [REDACTED] b6 >

Cc: Beumont-Mauviel, Maria [JRDUS] [REDACTED] b6 ; Trank, Christina [REDACTED] b6

Subject: RE: Corporate Communications Contacts at Allergan/AbbVie and BMS

Brian,

Thanks for the quick response.

Chrissy,

GADB0000003001

Once I've heard from David on the AbbVie/Allergan contact, I'll put you all in touch with each other.

Take care,

Rich

Richard Melsheimer
Medical Affairs
Compound Development Team Leader (CDTL) - Remicade
Janssen Biologics, BV
Leiden, the Netherlands

Mobile tel: b6 7
Email: b6

From: Gavin, Brian b6
Sent: Friday, June 19, 2020 7:44 PM
To: Melsheimer, Rich [CNTNL] b6 ; 'Bharucha_David' b6 >; Sadeh, Jonathan < b6
Cc: Beumont-Mauviel, Maria [JRDUS] < b6 ; Trank, Christina b6 >
Subject: [EXTERNAL] RE: Corporate Communications Contacts at Allergan/AbbVie and BMS

WARNING: This email originated from outside the company. Do not click on links unless you recognize the sender and have confidence the content is safe. If you have concerns about this email, send it as an attachment to SuspiciousEmail@ITS.JNJ.COM.

Sure Rich, For BMS the contact in corporate communications would be Christina (Chrissy) Trank.

Brian

From: Melsheimer, Rich [CNTNL] b6
Sent: Friday, June 19, 2020 1:27 PM
To: 'Bharucha_David' < b6 Gavin, Brian < b6 Sadeh, Jonathan b6 >
Cc: Beumont-Mauviel, Maria [JRDUS] b6 >
Subject: Corporate Communications Contacts at Allergan/AbbVie and BMS

[Use CAUTION when opening links/attachments]

David, Jonathan and Brian,

As mentioned on today's call, you probably have seen the article in this week's Pink Sheet on the ACTIV-1-2-3-4 program (attached). It is based on an interview with David Wholley, the Sr VP of Research Partnerships at FNIH. Our drugs were not mentioned, but some details on ACTIV-1 were provided, the key text being:

Whooley said ACTIV's working group on clinical therapeutics looked at 400 agents that were culled from six or seven public databases and submissions from investigators. It narrowed the list to 170, selecting those that have a mechanism of action related to COVID-19, are in supply, and are not being tested elsewhere. They reduced that list to 39 agents and selected three host-targeted immune modulators and three anticoagulants to bring into a set of master protocols, which are to launch in the next 30 days.

ACTIV's first master protocol, dubbed ACTIV-1, is a Phase III trial testing three host-targeted immune modulators in approximately 2,000 COVID patients who are more than 18 years old. The inpatient study will be conducted by a contract research organization in the US and globally. The investigational new drug application will likely be held by the National Institute of Allergy and Infectious Diseases.

Prompted by this, my internal corporate communications contact asked me if I could get from you the names of her counterparts at Allergan/AbbVie and BMS to align on communications/announcement plans for ACTIV-1. Would this be possible? If so, please forward the contacts' names to me and I will put them in touch with our Corp Comms lead on this project.

Thanks and have a nice weekend,

Rich

Richard Melsheimer
Medical Affairs
Compound Development Team Leader (CDTL) - Remicade
Janssen Biologics, BV
Leiden, the Netherlands

Mobile tel: b6
Email: b6

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 7/9/2020 2:26:25 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV consents and protocols

Thanks, Michelle.

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct

b6

Mobile:

b6

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, July 9, 2020 10:23 AM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Cc: Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV consents and protocols

Stacey,

I don't have an answer about how patient level data would be shared and can't tell you what, if or when to change the consents. Sorry.

Thanks for clarification on who is the sponsor.

Best,

Michelle

From: Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Sent: Wednesday, July 8, 2020 8:52 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV consents and protocols

Thanks, Michelle,

When will we know if these modifications need to be made or do I need to let the protocol teams know they need to change these proactively. I ask because ACTIV-2 has already been returned to FDA for final review, so this would most likely be a post approval, pre-activation protocol amendment. Just need to know if we need to do it immediately or if it can be done later.

On your other question, NIAID is the domestic sponsor UMN is the international sponsor.

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 Mobile: [REDACTED] b6

From: Culp, Michelle (NIH/OD) [E] [REDACTED] b6 >
Sent: Wednesday, July 8, 2020 12:41 PM
To: Adam, Stacey (FNIH) [T] [REDACTED] b6 >
Cc: Wholley, David (FNIH) [T] [REDACTED] b6 Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Subject: RE: ACTIV consents and protocols

Stacey,

Thanks for the 2 draft consents. The ACTIV-2 (ACTG outpatient) consent is really well written.

- The ACTIV-2 consent does not make any statements about sharing the subjects data (patient level data) with anyone.
- The ACTIV-3 (inpatient) consent states subject data may be shared with other COVID19 researchers. "UMN may share your data and specimens with other people who study COVID-19. UMN will remove any information that could possibly be used to identify you before sharing. This is called "anonymizing the data." We will not ask you for additional consent for this sharing. UMN will only share data and specimens for research projects that are approved by the group that is conducting this study."

If ACTIV patient level data is going to be deposited into DataCelerate (or elsewhere) consent language will need to be amended.

A couple unsolicited comments that you can take or disregard:

- The ACTIV-3 consent on page 1 says the study is sponsored by UMN. Do they mean IND Sponsor?
- The ACTIV-3 consent allows pregnant women to enroll, but disallows pregnancy (women and their partners) during the trial. ACTIV-2 (using the same or similar products) does not prohibit pregnancy during the trial. This seems incongruous.

From: Adam, Stacey (FNIH) [T] [REDACTED] b6
Sent: Tuesday, July 7, 2020 4:42 PM
To: Culp, Michelle (NIH/OD) [E] [REDACTED] b6
Subject: RE: ACTIV consents and protocols

Hi Michelle,

Here are the two for ACTIV-2 and ACTIV-3. ACTIV-1 is still working on theirs and I don't have access to ACTIV-4.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 Mobile: [REDACTED] b6

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Tuesday, July 7, 2020 12:51 PM
To: Wholley, David (FNIH) [T] b6 >; Adam, Stacey (FNIH) [T] < b6 >; Santos, Michael (FNIH) [T] b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 >; Parker, Ashley (NIH/OD) [E] b6 >; Menetski, Joseph (FNIH) [T] b6
Subject: ACTIV consents and protocols

Dear David, Stacey and Mike,

I'm continuing my conversations with DataCelerate and Gates Workbench about sharing patient and summary level data. To move forward with sharing any ACTIV trial data, we need to know how this is written in the informed consent documents and protocols with regard to data sharing, privacy, data access and future use of data.

Would you be able to provide me the consents and protocols so we can review that text?

Thank you.

Best regards,
Michelle

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 7/7/2020 8:30:54 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]
Subject: RE: ACTIV consents and protocols

Hi Michelle,

I will work to pull the most recent ICFs for the trials that have them ready. I will say though, they are likely to cover this data release specifically as the teams will not have known this was a possibility. There may however be acceptable general language that covers.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [REDACTED] b6 Mobile: [REDACTED] b6

From: Culp, Michelle (NIH/OD) [E] <[REDACTED] b6>
Sent: Tuesday, July 7, 2020 12:51 PM
To: Wholley, David (FNIH) [T] <[REDACTED] b6> Adam, Stacey (FNIH) [T] <[REDACTED] b6> Santos, Michael (FNIH) [T] <[REDACTED] b6>
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6> Parker, Ashley (NIH/OD) [E] <[REDACTED] b6> Menetski, Joseph (FNIH) [T] <[REDACTED] b6>
Subject: ACTIV consents and protocols

Dear David, Stacey and Mike,

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Thank you.
Best regards,
Michelle

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 7/7/2020 6:00:58 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: ACTIV consents and protocols

Mike,
That would be great. Thank you.
-Michelle

From: Santos, Michael (FNIH) [T] <[REDACTED]> **b6**
Sent: Tuesday, July 7, 2020 1:22 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**
Subject: RE: ACTIV consents and protocols

Hi Michelle,

CoVPN would hold those for the vaccine trials that they are running. I'm happy to send a note connecting you with Larry Corey and John Mascola to connect you on that topic if you'd like.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, July 7, 2020 12:51 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Adam, Stacey (FNIH) [T] <[REDACTED]> **b6**; Santos, Michael (FNIH) [T] <msa@fnih.gov> **b6**
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**; >; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Menetski, Joseph (FNIH) [T] <[REDACTED]> **b6**
Subject: ACTIV consents and protocols

Dear David, Stacey and Mike,
I'm continuing my conversations with DataCelerate and Gates Workbench about sharing patient and summary level data. To move forward with sharing any ACTIV trial data, we need to know how this is written in the informed consent documents and protocols with regard to data sharing, privacy, data access and future use of data.

Would you be able to provide me the consents and protocols so we can review that text?

Thank you.
Best regards,
Michelle

From: Tucker, Jessica (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BAF4AE78D90412DBEFBFFB5E52C31A4-TUCKERJM]
Sent: 7/1/2020 11:34:58 AM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Wann, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35a10ade04db43c997fbbc28531571fc-wanneg]
Subject: RE: plan for my response on proposed AMP MOU Amendment

Thanks for letting me know.

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, June 29, 2020 6:41 PM
To: Tucker, Jessica (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Wann, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: plan for my response on proposed AMP MOU Amendment

Jessica,

I spoke to Ann Martin and Jackie Godin today about a proposal from FNIH to amend the AMP MOU. They propose 3 changes; the first one is fine (save for some technical edits OGC will provide) and desirable—we won't have to amend the MOU every time there is a new project. The second and third provisions are not OK. Provisions 2 & 3 are vague and we are not sure of the exact intent, but based on plain readings, we would not want to agree to them for reasons I can describe when we talk. Provisions 2 & 3 are also not needed to get schizophrenia and gene therapy launched.

So my plan is to write back to FNIH and say that the first provision sounds like a great idea, we'd like to make that change right away to get set for the schizophrenia and gene therapy projects, and we just have a few technical edits that OGC is working on. For the second and third, I would ask them what problems are that they are trying to address and what are they trying to accomplish? Then later--unless their responses change our views--we would want to push back and say no.

We can talk about this Weds a.m.—tomorrow is looking really bad for me anyway—but I wanted to write this down while the OGC discussion was still fresh in my head.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, June 15, 2020 5:11 PM
To: Godin, Jacquelyn (NIH/OD) [E] <[REDACTED]> **b6** Martin, Ann (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Wann, Ellen (NIH/OD) [E] <[REDACTED]> **b6**; Jessica (NIH/OD) Tucker [E] <[REDACTED]> **b6**
Subject: FW: AMP MOU Amendment 1 (AMP) [REDACTED] **b4**

Hi Jackie and Ann,

Can you take a look at proposed amendment to the AMP MOU? The basic idea of not amending the MOU with each new project seems good to me (e.g. there is a gene therapy project with NCATS and FDA coming along), but I don't like the tone of the rest. At a quick glance the second provision seems a little heavy-handed to me, but maybe that is standard language now. The 3rd provision sounds like they don't trust us.

In terms of priorities, I think the ACTIV antitrust policy review is more urgent, but I'm passing this along as I'm on leave the rest of this week.

Thanks,
Ellen

From: Appelmans, Eline (FNIH) [T] b6
Sent: Monday, June 15, 2020 4:54 PM
To: Gadbois, Ellen (NIH/OD) [E] b
Cc: Godin, Jacquelyn (NIH/OD) [E] b6 . Wholley, David (FNIH) [T] b6 >; Master, Catherine (FNIH) [T] < b6
Subject: AMP MOU Amendment 1 (AMP- b4)

Dear Ellen,

b4

Kind Regards,
Eline

Eline Appelmans, MD, MPH, BMedSci
Program Manager Neuroscience Research Partnerships
Foundation for the National Institutes of Health
Work Cell: (b6) 1 [fnih.org](mailto:eline@fnih.org)
Personal Cell: (b6)
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 6/4/2020 9:55:30 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: Data-Sharing

Thank you!

-----Original Message-----

From: Wholley, David (FNIH) [T] <[REDACTED] b6 >
Sent: Thursday, June 4, 2020 5:23 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED] b6 >; Gadbois, Ellen (NIH/OD) [E]
Subject: FW: Data-Sharing

Taking the liberty of sending you this. I also emailed my thoughts to Larry.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew <[REDACTED] b6 >; Paul Stoffel <[REDACTED] b6 >; Heatherington, Anne <[REDACTED] b6 >
Cc: Mikael Dolsten MD PhD <[REDACTED] b6 >; Wholley, David (FNIH) [T] <[REDACTED] b6 >
Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 >; Freire, Maria (FNIH) [T] <[REDACTED] b6 >;
Austin, Christopher (NIH/NCATS) [E] <[REDACTED] b6 >
Subject: RE: Data-Sharing

Hi Andy,

Thanks for your leadership on these critical data sharing issues -- and yes, a group of us from NIH/FNIH would very much like to meet with you, Anne, and any others that you think would assist the conversation. I have already asked my principal Deputy, Dr. Larry Tabak, to assemble the right NIH group to take part in this conversation, and I will count on David to figure out who should attend from FNIH.

One of the items that I know the group will want to know more about is the Gates Accelerator -- it's been hard to get a sense of the architecture and ease of use. Is there a beta test model available that we could try out?

Best, Francis

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From: Plump, Andrew <[REDACTED] b6 >
Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >; Paul Stoffel <[REDACTED] b6 >;
Heatherington, Anne <[REDACTED] b6 >
Cc: Mikael Dolsten MD PhD <[REDACTED] b6 >; Wholley, David (FNIH) [T] <[REDACTED] b6 >
Subject: Data-Sharing

Hi Francis and Paul,

Terrific ACTIV leadership meeting yesterday. Remarkable progress.

Following up on the HEVER dialogue on data-sharing. I know you are fully on board with the need for essentially real-time data sharing of emerging clinical trial data, and there is a team that has identified a framework that should work for the NIH. While there may be arcane US government provisions to which we are not aware, the privacy considerations are at least as stringent within industry, and essentially all companies have agreed to the framework Anne presented, so I do not imagine roadblocks.

My suggestion is that Anne and members of the data-sharing group meet with you, David, and/or whomever else you would suggestion from NIH/ACTIV to bring you up to speed and figure out a path forward.

Thanks,
Andy

Sent from my iPad

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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 6/17/2020 12:09:08 PM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Ann,
Thank you for the update!

Best regards,
Michelle

From: Martin, Ann (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, June 16, 2020 6:35 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hello, Michelle,

[REDACTED] **b5**
[REDACTED] **b5** I will stay on top
of it and get back to you as soon as I possibly can.

Thank you,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
[REDACTED] **b6** (main)
[REDACTED] **b6**

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From: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Tuesday, June 16, 2020 4:30 PM
To: Martin, Ann (NIH/OD) [E] <[REDACTED]> **b6** Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,
Have you heard anything back from your OGC colleagues on [REDACTED] **b5** If not, I'll check back in later in the week.

Thank you!
Best regards,
Michelle

GADB0000003278

From: Martin, Ann (NIH/OD) [E] b6
Sent: Friday, June 12, 2020 8:48 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen,
Thanks for forwarding b5 I am consulting on this internally within OGC and will get back to you ASAP. I will be sure to include Michelle. (It is nice to meet you by email, Michelle, and I look forward to working with you).
Best,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892

b6 (main)
b6

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From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, June 11, 2020 3:40 PM
To: Martin, Ann (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: FW: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi Ann,
Here is b5, as explained by David Wholley below. He asks for me to let him know b5

Copying Michelle, my OSP ACTIV buddy. FYI I will be on leave starting next Tuesday and won't have much email access, so can you please include Michelle in your response?
Thanks,
Ellen

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, June 11, 2020 3:33 PM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Klock, Kevin (FNIH) [T] b6
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen —

b5

Thanks for your help.

David

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 6/12/2020 12:58:36 PM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV Antitrust Guidelines 6-11-20 for external review

Ann,
Nice to meet you, too! Someday, when NIH solves COVID, I look forward to meeting you.

Best regards,
Michelle

From: Martin, Ann (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Friday, June 12, 2020 8:48 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6**
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Best,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
[REDACTED] **b6** (main)
[REDACTED] **b6**

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Hi Ann,
Here is [REDACTED] **b5** as explained by David Wholley below. He asks for me to let him know [REDACTED] **b5**

Copying Michelle, my OSP ACTIV buddy FYI I will be on leave starting next Tuesday and won't have much email access, so can you please include Michelle in your response?
Thanks,

GADB0000003340

Ellen

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To: Gadbois, Ellen (NIH/OD) [E] < b6 >
Cc: Klock, Kevin (FNIH) [T] b6 >
Subject: ACTIV Antitrust Guidelines 6-11-20 for external review

Hi, Ellen –

b5

Thanks for your help.

David

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Sent: 6/15/2020 9:44:58 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Godin, Jacquelyn (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc88d464efc34115904f29a975aeeb85-godinja]
CC: Wann, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35a10ade04db43c997fbbc28531571fc-wanneg]; Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0ff5e52c31a4-tuckerjm]
Subject: RE: AMP MOU Amendment 1 b4

Thanks, Ellen. We will take a look and plan to connect with you on the AMP MOU amendments once you are back from leave. I hope you enjoy your time away from the virtual office.

Best,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

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Cc: Wann, Ellen (NIH/OD) [E] <b6> Tucker, Jessica (NIH/OD) [E] <b6>
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Hi Jackie and Ann,

Can you take a look at proposed amendment to the AMP MOU? The basic idea of not amending the MOU with each new project seems good to me (e.g. there is a gene therapy project with NCATS and FDA coming along), but I don't like the tone of the rest. At a quick glance the second provision seems a little heavy-handed to me, but maybe that is standard language now. The 3rd provision sounds like they don't trust us.

In terms of priorities, I think the ACTIV antitrust policy review is more urgent, but I'm passing this along as I'm on leave the rest of this week.

Thanks,
Ellen

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Sent: Monday, June 15, 2020 4:54 PM
To: Gadbois, Ellen (NIH/OD) [E] <b6> >

Cc: Godin, Jacquelyn (NIH/OD) [E] <[REDACTED]>
Catherine (FNIH) [T] [REDACTED]
Subject: AMP MOU Amendment 1 (AMP- [REDACTED])

b6

Wholley, David (FNIH) [T] <[REDACTED]>

b6

Master,

b4

Dear Ellen,

b5

Kind Regards,
Eline

Eline Appelmans, MD, MPH, BMedSci
Program Manager Neuroscience Research Partnerships
Foundation for the National Institutes of Health
Work Cell: [REDACTED] [\[REDACTED\]@fnih.org](mailto:[REDACTED]@fnih.org)
Personal Cell: [REDACTED]
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 6/5/2020 2:32:16 PM
To: Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]
Subject: RE: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in
Attachments: Deloitte Research on Platforms and Data Strategy for ACTIV 05302020 v2 MC Comments.docx

Lyric and now including Carrie,
Attached is a Data Platform assessment prepared by Deloitte at the request of FNIH. I added my thoughts in the comment bubbles.

My main question is "What is the goal of data sharing in real-time and sharing with whom?" (Ok, that's 2 questions.)

Someone, maybe Deloitte, is gathering requirements for the data sharing platform.

-Michelle
(sorry to the others for the repeat message)

-----Original Message-----

From: Jorgenson, Lyric (NIH/OD) [E] <[REDACTED] b6>
Sent: Friday, June 5, 2020 9:52 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6>; Wolinetz, Carrie (NIH/OD) [E] <[REDACTED] b6>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED] b6>; Tucker, Jessica (NIH/OD) [E] <[REDACTED] b6>
Subject: RE: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in

Oof

I'm looping in Carrie. I think she and I need to discuss who would be the right person to put on this.

-----Original Message-----

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6>
Sent: Friday, June 5, 2020 9:48 AM
To: Jorgenson, Lyric (NIH/OD) [E] <[REDACTED] b6>
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED] b6>; Tucker, Jessica (NIH/OD) [E] <[REDACTED] b6>
Subject: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in

Lyric--Jessica will bring this to your attention later but this is likely to be moving super fast. Bottom line: I think SciDASH needs to be brought in to help advise LT on an effort he is leading to figure out platform(s) and rules for data sharing in ACTIV. I can help provide context and Michelle understands a lot here, but we need someone who can speak to any application of NIH policy on data sharing & privacy for data from the ACTIV partners. At least some of the data will be from NIH-funded research. People are trying to sort out the IT capabilities of various data sharing platforms for both summary and individual level data, and what data sharing and privacy rules apply. Lots of cooks in the kitchen already but someone needs to authoritatively sort out NIH policy on privacy and data sharing. Also there is discussion about whether CT.gov has a role--seems like no one thinks CT.gov is useful, and FC wants to know why not, and FNIH thinks this is an NIH thing to sort out. I don't really understand the policy landscape. Michelle (cc'd) has a better grip on the CT.gov situation and the networks likely to be generating data, but we both think SciDASH needs to be part of this. If Taunton is involved, he could be thinking about HIPPA too.

See emails from FC and Andy Plump (Takeda) below.

Things are moving really fast. Big monoclonal antibody summit Tuesday and everyone is trying to get ducks in a row before then.

-----Original Message-----

From: Wholley, David (FNIH) [T] <[REDACTED] b6 >
Sent: Thursday, June 4, 2020 5:23 PM
To: Culb. Michelle (NIH/OD) [E] <[REDACTED] b6 > Gadbois, Ellen (NIH/OD) [E]
<[REDACTED] b6 >
Subject: FW: Data Sharing

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Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew <[REDACTED] b6 > Paul Stoffel <[REDACTED] b6 > Heatherington, Anne
<[REDACTED] b6 >
Cc: Mikael Dolsten MD PhD <[REDACTED] b6 > Wholley, David (FNIH) [T] <[REDACTED] b6 >
Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 > Freire, Maria (FNIH) [T] <[REDACTED] b6 >
Austin, Christopher (NIH/NCATS) [E] <[REDACTED] b6 >
Subject: RE: Data-Sharing

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One of the items that I know the group will want to know more about is the Gates Accelerator -- it's been hard to get a sense of the architecture and ease of use. Is there a beta test model available that we could try out?

Best, Francis

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Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 > ; Paul Stoffel <[REDACTED] b6 >
Heatherington, Anne <[REDACTED] b6 >
Cc: Mikael Dolsten MD PhD <mikael.dolsten@pfizer.com>; Wholley, David (FNIH) [T] <[REDACTED] b6 >
Subject: Data-Sharing

Hi Francis and Paul,

Terrific ACTIV leadership meeting yesterday. Remarkable progress.

Following up on the HEVER dialogue on data-sharing. I know you are fully on board with the need for essentially real time data sharing of emerging clinical trial data, and there is a team that has identified a framework that should work for the NIH. While there may be arcane US government provisions to which we are not aware, the privacy considerations are at least as stringent within industry, and essentially all companies have agreed to the framework Anne presented, so I do not imagine roadblocks.

My suggestion is that Anne and members of the data-sharing group meet with you, David, and/or whomever else you would suggestion from NIH/ACTIV to bring you up to speed and figure out a path forward.

Thanks,
Andy

Sent from my iPad

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA74284158B86087D08B628E6F-MELENCIOC]
Sent: 5/18/2020 8:26:23 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboiset]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: Meet to discuss new liaison roles
Attachments: FNIH Covid Team List 05182020.docx

Hi Ellen and Michelle

Attached is the FNIH/Deloitte team list. I will send you the calendar invites for the Executive Committee call which is scheduled for May 20 3:30 p.m. – 5 p.m. and June 3 ACTIV Leadership Call which is scheduled for 12 – 1:30 p.m. I will add you to the distribution list for materials and meeting invites.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, May 18, 2020 3:54 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6 Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Subject: RE: Meet to discuss new liaison roles

That's very helpful—thanks.

From: Wholley, David (FNIH) [T] <[REDACTED]> b6 >
Sent: Monday, May 18, 2020 2:05 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6 >
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6 Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Subject: RE: Meet to discuss new liaison roles

Sure. I've been so busy I forgot to send the materials. Here are slides from our last several meetings. The "daily update" includes some of the near term meetings; Cheryl can give the schedule for the others. I have also attached the full rosters for the working groups. Cheryl, can you also please send the list of the FNIH/Deloitte support team members? Thanks

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Monday, May 18, 2020 1:36 PM
To: Wholley, David (FNIH) [T] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: Meet to discuss new liaison roles

Hi David,
I hope that you and your family is well.
I'm just checking to see if there are any materials ready for Michelle and me to review before Wednesday. I'm particularly interested in what the schedule looks like for the various working groups. I am not totally sure what I'll be doing as part of this, but it would be good to know about any key dates.
Thanks very much,
Ellen

From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, May 13, 2020 2:28 PM
To: Tabak, Lawrence (NIH/OD) [E] < b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6 ; Gadbois, Ellen (NIH/OD) [E] < b6 Burrus-Shaw, Cyndi (NIH/OD) [E] b6 >; Simon, Dina (NIH/OD) [C] b6 >; Adam, Stacey (FNIH) [T] b6 >; Santos, Michael (FNIH) [T] b6 ; Menetski, Joseph (FNIH) [T] b6 >; Tountas, Karen (FNIH) [T] < b6 Freire, Maria (FNIH) [T] b6 >; James, Stephanie (FNIH) [T] b6
Subject: RE: Meet to discuss new liaison roles

Excellent news, Larry! Welcome aboard to Michelle and Ellen. I think it would make sense for us to include my four key project leads: Stacey Adam, Joe Menetski, Karen Tountas, and Mike Santos on the call so we can hit the ground running. OK for me to send ahead some materials, like the slides and notes from the last LT meeting, to assist in getting them oriented? Or are you sharing info with them in advance of the call? Cheryl Melencio can arrange schedules on our end.

Many thanks,
David

From: Tabak, Lawrence (NIH/OD) [E] b6
Sent: Wednesday, May 13, 2020 1:31 PM
To: Wholley, David (FNIH) [T] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 ; Gadbois, Ellen (NIH/OD) [E] b6 >; Burrus-Shaw, Cyndi (NIH/OD) [E] b6 >; Simon, Dina (NIH/OD) [C] b6
Subject: Meet to discuss new liaison roles

David,

As you discussed with Francis, Michelle Culp and Ellen Gadbois stand ready to assist with enhancing communications/actions between NIH and FNIH for the ACTIV program. Francis, Carne, and I have discussed, and for the purpose of this activity Michelle and Ellen will use me as their point of contact at NIH.

I would appreciate holding an initial meeting for the three of us with you and any other members of your team you wish to include to scope out initial activities etc. A member of my team will reach out to set up a time.

Best wishes,
Larry

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 6/5/2020 2:23:47 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]
CC: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0fb5e52c31a4-tuckerjm]
Subject: RE: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in
Attachments: Deloitte Research on Platforms and Data Strategy for ACTIV 05302020 v2 MC Comments.docx

Lyric,
Attached is a Data Platform assessment prepared by Deloitte at the request of FNIH. I added my thoughts in the comment bubbles.

My main question is "What is the goal of data sharing in real-time and sharing with whom?" (Ok, that's 2 questions.)

Someone, maybe Deloitte, is gathering requirements for the data sharing platform.

-Michelle

-----Original Message-----

From: Gadbois, Ellen (NIH/OD) [E] <b6>
Sent: Friday, June 5, 2020 9:48 AM
To: Jorgenson, Lyric (NIH/OD) [E] <b6>
Cc: Culp, Michelle (NIH/OD) [E] <b6>; Tucker, Jessica (NIH/OD) [E] <b6>
Subject: For LJ consideration today: LT is putting together a data-sharing group for ACTIV and I think SciDASH needs to be brought in

Lyric - Jessica will bring this to your attention later but this is likely to be moving super fast. Bottom line: I think SciDASH needs to be brought in to help advise LT on an effort he is leading to figure out platform(s) and rules for data sharing in ACTIV. I can help provide context and Michelle understands a lot here, but we need someone who can speak to any application of NIH policy on data sharing & privacy for data from the ACTIV partners. At least some of the data will be from NIH funded research. People are trying to sort out the IT capabilities of various data sharing platforms for both summary and individual level data, and what data sharing and privacy rules apply. Lots of cooks in the kitchen already but someone needs to authoritatively sort out NIH policy on privacy and data sharing. Also there is discussion about whether CT.gov has a role seems like no one thinks CT.gov is useful, and FC wants to know why not, and FNIH thinks this is an NIH thing to sort out. I don't really understand the policy landscape. Michelle (cc'd) has a better grip on the CT.gov situation and the networks likely to be generating data, but we both think SciDASH needs to be part of this. If Taunton is involved, he could be thinking about HIPPA too.

See emails from FC and Andy Plump (Takeda) below.

Things are moving really fast. Big monoclonal antibody summit Tuesday and everyone is trying to get ducks in a row before then.

-----Original Message-----

From: Wholley, David (FNIH) [T] <b6>
Sent: Thursday, June 4, 2020 5:23 PM
To: Culp, Michelle (NIH/OD) [E] <b6>; Gadbois, Ellen (NIH/OD) [E] <b6>
Subject: FW: Data Sharing

Taking the liberty of sending you this. I also emailed my thoughts to Larry.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <b6>
Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew <b6>; Paul Stoffel <b6>; Heatherington, Anne <b6>
Cc: Mikael Dolsten MD PhD <b6>; Wholley, David (FNIH) [T] <b6>
Tabak, Lawrence (NIH/OD) [E] <b6>; Freire, Maria (FNIH) [T] <b6>
Austin, Christopher (NIH/NCATS) [E] <b6>

Subject: RE: Data-Sharing

Hi Andy,

Thanks for your leadership on these critical data sharing issues -- and yes, a group of us from NIH/FNIH would very much like to meet with you, Anne, and any others that you think would assist the conversation. I have already asked my principal Deputy, Dr. Larry Tabak, to assemble the right NIH group to take part in this conversation, and I will count on David to figure out who should attend from FNIH.

One of the items that I know the group will want to know more about is the Gates Accelerator -- it's been hard to get a sense of the architecture and ease of use. Is there a beta test model available that we could try out?

Best, Francis

-----Original Message-----

From: Plump, Andrew <[REDACTED]> b6
Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 ; Paul Stoffel <[REDACTED]> b6
Heatherington, Anne <[REDACTED]> b6
Cc: Mikael Dolsten MD PhD <[REDACTED]> b6 ; Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: Data-Sharing

Hi Francis and Paul,

Terrific ACTIV leadership meeting yesterday. Remarkable progress.

Following up on the HEVER dialogue on data-sharing. I know you are fully on board with the need for essentially real-time data sharing of emerging clinical trial data, and there is a team that has identified a framework that should work for the NIH. While there may be arcane US government provisions to which we are not aware, the privacy considerations are at least as stringent within industry, and essentially all companies have agreed to the framework Anne presented, so I do not imagine roadblocks.

My suggestion is that Anne and members of the data-sharing group meet with you, David, and/or whomever else you would suggestion from NIH/ACTIV to bring you up to speed and figure out a path forward.

Thanks,
Andy

Sent from my iPad

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GADB0000003651

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C18522-MYLESR]
Sent: 6/3/2020 11:21:21 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Higgins, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfde4719d7ac48e4a60b2ecd1969a716-higgins]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]
Subject: RE: ATTENTION: ACTIV Communication Items

Thanks for the helpful feedback. We'll proceed with making these changes, but welcome additional feedback, including from the folks David looped in (Menetski, Adam, Tountas, Santos) on any changes to the messaging.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, June 3, 2020 6:40 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]> Myles, Renate (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED]> Fine, Amanda (NIH/OD) [E] <[REDACTED]> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> Hallett, Adrienne (NIH/OD) [E]

< b6 Higgins, Lauren (NIH/OD) [E] < b6 Gadbois, Ellen (NIH/OD) [E]
< b6 Brodd, Lauren (NIH/OD) [E] < b6 Meltzer, Abbey (FNIH) [T]
< b6 Gorman, Greta (FNIH) [T] < b6 Menetski, Joseph (FNIH) [T]
< b6 Adam, Stacey (FNIH) [T] < b6 Tountas, Karen (FNIH) [T] < b6
Santos, Michael (FNIH) [T] < b6 James, Stephanie (FNIH) [T] < b6

Subject: RE: ATTENTION: ACTIV Communication Items

Hi Renate et al.,

Thanks for doing all this! It's great to get these materials out there.

I agree with the thoughtful comments from Ashley and David.

This is not a big deal, but I'm not crazy about the slide template. Having those large hexagons only half included, looming at the top of the slide, seems weird, even a bit ominous. And the use of smaller hexagons in slides 5 - 8 to indicate specific points for each WG, some filled in, and some not, makes one wonder what the significance of the shading is. Are the filled in hexagons supposed to indicate that those tasks are done? The outlined hexagons are still a work in progress? Actually, the differences don't seem to have any significance, so they are distracting. Fill them all in, or fill none of them in.

Finally (and sorry for being picky), the choice of image for the clinical trials working group (a microscope) seems inappropriate for the work this group is doing. Maybe a researcher and some research participants?

Francis

From: Wholley, David (FNIH) [T] < b6
Sent: Tuesday, June 2, 2020 9:01 PM
To: Parker, Ashley (NIH/OD) [E] < b6 >; Myles, Renate (NIH/OD) [E] < b6 >; Collins, Francis (NIH/OD) [E] < b6 >; Tabak, Lawrence (NIH/OD) [E] < b6 >; Freire, Maria (FNIH) [T] < b6 >; Wolinetz, Carrie (NIH/OD) [E] < b6 >
Cc: Burklow, John (NIH/OD) [E] < b6 >; Fine, Amanda (NIH/OD) [E] < b6 >; Wojtowicz, Emma (NIH/OD) [E] < b6 >; Hallett, Adrienne (NIH/OD) [E] < b6 >; Higgins, Lauren (NIH/OD) [E] < b6 >; Gadbois, Ellen (NIH/OD) [E] < b6 >; Brodd, Lauren (NIH/OD) [E] < b6 >; Meltzer, Abbey (FNIH) [T] < b6 >; Gorman, Greta (FNIH) [T] < b6 >; Menetski, Joseph (FNIH) [T] < b6 >; Adam, Stacey (FNIH) [T] < b6 >; Tountas, Karen (FNIH) [T] < b6 >; Santos, Michael (FNIH) [T] < b6 >; James, Stephanie (FNIH) [T] < b6 >
Subject: RE: ATTENTION: ACTIV Communication Items

Sorry, file attached this time. David

From: Wholley, David (FNIH) [T]
Sent: Tuesday, June 2, 2020 8:56 PM
To: Parker, Ashley (NIH/OD) [E] < b6 >; Myles, Renate (NIH/OD) [E] < b6 >; Collins, Francis (NIH/OD) [E] < b6 >; Tabak, Lawrence (NIH/OD) [E] < b6 >; Freire, Maria (FNIH) [T] < b6 >; Wolinetz, Carrie (NIH/OD) [E] < b6 >
Cc: Burklow, John (NIH/OD) [E] < b6 >; Fine, Amanda (NIH/OD) [E] < b6 >; Wojtowicz, Emma (NIH/OD) [E] < b6 >; Hallett, Adrienne (NIH/OD) [E] < b6 >; Higgins, Lauren (NIH/OD) [E] < b6 >; Gadbois, Ellen (NIH/OD) [E] < b6 >

< [b6] Brodd, Lauren (NIH/OD) [E] < [b6] Meltzer, Abbey (FNIH) [T]
<ameltzer@fnih.org>; Gorman, Greta (FNIH) [T] [b6] ; Menetski, Joseph (FNIH) [T]
< [b6] Adam, Stacey (FNIH) [T] [b6] . Tountas, Karen (FNIH) [T] [b6] >;
Santos, Michael (FNIH) [T] [b6] ; James, Stephanie (FNIH) [T] [b6]
Subject: RE: ATTENTION: ACTIV Communication Items

Hi Ashley and Renate:

Please see my reply comments to Ashley's comment. I am copying our FNIH staff (Menetski, Adam, Tountas, Santos) who are supporting the ACTIV Working Groups for their take on the accuracy of what I've commented on, and any other refinements that may be appropriate. Thanks, David

From: Parker, Ashley (NIH/OD) [E] [b6] >>
Sent: Tuesday, June 2, 2020 6:48 PM
To: Myles, Renate (NIH/OD) [E] < [b6] Collins, Francis (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E] [b6] >; Freire, Maria (FNIH) [T] [b6] ; Wholley, David (FNIH) [T] < [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6] >; Fine, Amanda (NIH/OD) [E] [b6] >; Wojtowicz, Emma (NIH/OD) [E] < [b6] Hallett, Adrienne (NIH/OD) [E] [b6] >; Higgins, Lauren (NIH/OD) [E] [b6] >; Gadbois, Ellen (NIH/OD) [E] [b6]
[b6] Brodd, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T]
[b6] >; Gorman, Greta (FNIH) [T] [b6] >
Subject: RE: ATTENTION: ACTIV Communication Items

Hi Renate,

Looks great! Please see attached comments on the social media language and slides given recent updates.

Thank you,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, June 2, 2020 5:58 PM
To: Collins, Francis (NIH/OD) [E] < [b6] >; Tabak, Lawrence (NIH/OD) [E] [b6] >; Freire, Maria (FNIH) [T] < [b6] Wholley, David (FNIH) [T] < [b6] Wolinetz, Carrie (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] < [b6]
Cc: Burklow, John (NIH/OD) [E] [b6] Fine, Amanda (NIH/OD) [E] [b6] Wojtowicz, Emma (NIH/OD) [E] < [b6] Hallett, Adrienne (NIH/OD) [E] [b6] >; Higgins, Lauren (NIH/OD) [E] [b6] >; Gadbois, Ellen (NIH/OD) [E] [b6] >; Brodd, Lauren (NIH/OD) [E] < [b6] Meltzer, Abbey (FNIH) [T] [b6] Gorman, Greta (FNIH) [T] [b6]
Subject: ATTENTION: ACTIV Communication Items

Good evening:

I wanted to share a few items for your awareness and attention:

- 1) Tomorrow we will push the new designs of the ACTIV website and will promote the webpage via an NIH.gov homepage slide and social media. The social media language emphasizes that ACTIV aims to accelerate the development of vaccines and treatments for COVID-19 by streamlining administrative processes while maintaining rigorous safety standards. The homepage slide and social media language are attached.
- 2) Tomorrow, we expect the NYT to run a story on the five candidates selected by Operation Warp Speed. NYT says they've verified the five candidates from numerous sources, although HHS has said on the record that they will not confirm involvement in the initial group of vaccines unless a company is bound by fiduciary requirements to

report contractual agreements. From what I can find, HHS has confirmed the following vaccine candidates: Jansen, Moderna, and AstraZeneca under OWS.

- 3) We've received numerous requests from NIH Institutes and Centers for general ACTIV slides that they could incorporate into their slide decks for Councils, etc. We've developed the attached slide deck using top line talking points. The graphic style mimics the new web graphics. Please let us know if you have any concerns with the slides or the messaging.

Best,
Renate

Renate Myles, MBA

Deputy Chief of Public Affairs
Office of Communications and Public Liaison
U.S. Department of Health
and Human Services
b6

From: McGarey, Barbara (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4DF3AF92FE3F4763AE92DC40DCB6DF60-MCGAREYB]
Sent: 6/13/2020 12:08:00 AM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: Re: ACTIV Draft Antitrust Guidelines

Perfect, thanks Ann,

Barb

From: "Martin, Ann (NIH/OD) [E]" [REDACTED] b6
Date: Friday, June 12, 2020 at 1:58:01 PM
To: "McGarcy, Barbara (NIH/OD) [C]" [REDACTED] b6 >
Cc: "Gadbois, Ellen (NIH/OD) [E]" [REDACTED] b6
Subject: RE: ACTIV Draft Antitrust Guidelines

Hi, Barb,

As a quick follow-up to Jackie's note below, I wanted to thank you for this information. I won't hesitate to reach out to discuss background, as needed, as we review.

I hope you and your family are safe and well these days!

Best,

Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

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From: Godin, Jacquelyn (NIH/OD) [E] <[REDACTED]> b6
Sent: Friday, June 12, 2020 1:48 PM
To: McGarey, Barbara (NIH/OD) [C] <[REDACTED]> b6
Cc: Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> b6 Martin, Ann (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: ACTIV Draft Antitrust Guidelines

Hi Barb,

Thanks for your email, and it was great to "see" you by video the other day. That's helpful to know. I am copying Ann Martin here because she is the lead in NIH for ACTIV.

Have a nice weekend,

-Jackie

GADB0000003786

Jacquelyn A. Godin, JD, MPH
Senior Attorney
NIH Branch, Public Health Division
HHS Office of the General Counsel
b6 (direct)
b6

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From: McGarey, Barbara (NIH/OD) [C] < b6 >
Sent: Friday, June 12, 2020 1:16 PM
To: Godin, Jacquelyn (NIH/OD) [E] < b6 >
Cc: Gadbois, Ellen (NIH/OD) [E] b6
Subject: ACTIV Draft Anti-trust Guidelines

Hi Jackie,

I understand that David Wholly of FNIH b5 to Ellen for NIH review, and that Ellen has forwarded them to OGC. Just wanted to let you both know that I was involved in the FNIH legal review and would be happy to provide any background and/or answer any questions that arise during your review, if I am able. This has certainly been an interesting and fast moving project.

Cheers,

Barb

Barbara McGarey, J.D.
Consultant
Foundation for the NIH
b6
b6
b6

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E2283685FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/13/2020 6:30:49 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; S.mon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]
Subject: Re: Meet to discuss new liaison roles

David,
Please send materials that you feel will be most helpful for orientation.
Thanks
Larry

From: "Wholley, David (FNIH) [T]" <[REDACTED]> **b6**
Date: Wednesday, May 13, 2020 at 2:27 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Culp, Michelle (NIH/OD) [E]" <[REDACTED]> **b6** "Gadbois, Ellen (NIH/OD) [E]" <[REDACTED]> **b6** "Burrus-Shaw, Cyndi (NIH/OD) [E]" <[REDACTED]> **b6** "Simon, Dina (NIH/OD) [C]" <[REDACTED]> **b6** "Adam, Stacey (FNIH) [T]" <[REDACTED]> **b6** "Santos, Michael (FNIH) [T]" <[REDACTED]> **b6** "Menetski, Joseph (FNIH) [T]" <[REDACTED]> **b6** "Tountas, Karen (FNIH) [T]" <[REDACTED]> **b6** "Freire, Maria (FNIH) [T]" <[REDACTED]> **b6** "James, Stephanie (FNIH) [T]" <[REDACTED]> **b6**
Subject: RE: Meet to discuss new liaison roles

Excellent news, Larry! Welcome aboard to Michelle and Ellen. I think it would make sense for us to include my four key project leads: Stacey Adam, Joe Menetski, Karen Tountas, and Mike Santos on the call so we can hit the ground running. OK for me to send ahead some materials, like the slides and notes from the last LT meeting, to assist in getting them oriented? Or are you sharing info with them in advance of the call? Cheryl Melencio can arrange schedules on our end.

Many thanks,
David

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, May 13, 2020 1:31 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Cc: Culp, Michelle (NIH/OD) [E] <[REDACTED]> **b6** Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> **b6** Burrus-Shaw, Cyndi (NIH/OD) [E] <[REDACTED]> **b6** Simon, Dina (NIH/OD) [C] <[REDACTED]> **b6**
Subject: Meet to discuss new liaison roles

David,

As you discussed with Francis, Michelle Culp and Ellen Gadbois stand ready to assist with enhancing communications/actions between NIH and FNIH for the ACTIV program. Francis, Carne, and I have discussed, and for the purpose of this activity Michelle and Ellen will use me as their point of contact at NIH.

I would appreciate holding an initial meeting for the three of us with you and any other members of your team you wish to include to scope out initial activities etc. A member of my team will reach out to set up a time.

Best wishes,
Larry

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 4:14:29 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: ACTIV Introduction

Hi Ellen,

I will send the invite for 2pm today.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: **b6** | Mobile: **b6**

From: Gadbois, Ellen (NIH/OD) [E] <**b6**>
Sent: Thursday, May 21, 2020 11:11 AM
To: Adam, Stacey (FNIH) [T] <**b6**>
Cc: Culp, Michelle (NIH/OD) [E] <**b6**> Santos, Michael (FNIH) [T] <**b6**>
Subject: RE: ACTIV Introduction

Hi Stacey,
David Wholley advised me to listening to (at least for now) all of the ACTIV Working Group meetings (but not the subgroups). Could you please send me the Therapeutics-Clinical outlook invitations? Do you have one today at 2? And then I look forward to hearing more of the story at 5 p.m.
Thanks,
Ellen

From: Adam, Stacey (FNIH) [T] **b6** >
Sent: Wednesday, May 20, 2020 6:18 PM
To: Culp, Michelle (NIH/OD) [E] **b6** Tountas, Karen (FNIH) [T] **b6** Santos, Michael (FNIH) [T] **b6** >; Gadbois, Ellen (NIH/OD) [E] **b6**
Cc: Tolman, Brett **b6**
Subject: RE: ACTIV Introduction

Happy to add, Ellen!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: **b6** | Mobile: **b6**

From: Culp, Michelle (NIH/OD) [E] b6 >
Sent: Wednesday, May 20, 2020 6:14 PM
To: Adam, Stacey (FNIH) [T] b6 >; Tountas, Karen (FNIH) [T] b6 >; Santos, Michael (FNIH) [T] b6
Cc: Tolman, Brett b6
Subject: RE: ACTIV Introduction

Can we include Ellen, if she's available and interested?

Ellen, I asked Adam, Karen and Stacey for an overview of their WGs.
Michelle

From: Adam, Stacey (FNIH) [T] b6
Sent: Wednesday, May 20, 2020 5:54 PM
To: Culp, Michelle (NIH/OD) [E] b6 ; Tountas, Karen (FNIH) [T] b6 ; Santos, Michael (FNIH) [T] b6
Cc: Tolman, Brett < b6
Subject: RE: ACTIV Introduction

Thanks, all!

Let's do tomorrow at 5pm then, on the off hope that may be we would all get to call it and early Friday on the holiday weekend?

I will send an invite to this group. Karen, I am going to invite Elizabeth, do you want me to invite Jonathan?

Thanks,
STacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 Mobile: b6

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Wednesday, May 20, 2020 5:21 PM
To: Adam, Stacey (FNIH) [T] < b6 Tountas, Karen (FNIH) [T] < b6 Santos, Michael (FNIH) [T] b6
Cc: Tolman, Brett < b6
Subject: RE: ACTIV Introduction

Both work for me, too.
Stacey, your day sounds busier than mine, so please pick what's easier for you.
-Michelle

From: Adam, Stacey (FNIH) [T] < b6
Sent: Wednesday, May 20, 2020 3:43 PM
To: Tountas, Karen (FNIH) [T] b6 Santos, Michael (FNIH) [T] b6 >; Culp, Michelle (NIH/OD) [E] b6

Cc: Tolman, Brett b6
Subject: RE: ACTIV Introduction

Thanks, Karen and Mike.

Michelle, please just let me know what will work for you.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 Mobile: b6

From: Tountas, Karen (FNIH) [T] b6
Sent: Wednesday, May 20, 2020 3:39 PM
To: Santos, Michael (FNIH) [T] <b6> Adam, Stacey (FNIH) [T] <b6> Culp, Michelle (NIH/OD) [E] b6 >
Cc: Tolman, Brett b6
Subject: RE: ACTIV Introduction

Either work for me as well.

From: Santos, Michael (FNIH) [T] b6
Sent: Wednesday, May 20, 2020 3:38 PM
To: Adam, Stacey (FNIH) [T] b6 >; Culp, Michelle (NIH/OD) [E] b6 Tountas, Karen (FNIH) [T] b6 >
Cc: Tolman, Brett b6
Subject: RE: ACTIV Introduction

Either works for me – thanks!

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Adam, Stacey (FNIH) [T] b6
Sent: Wednesday, May 20, 2020 3:31 PM
To: Culp, Michelle (NIH/OD) [E] b6 Santos, Michael (FNIH) [T] b6 Tountas, Karen (FNIH) [T] b6 >
Cc: Tolman, Brett b6
Subject: RE: ACTIV Introduction

Hi All,

Could I interest any one in 4-5pm on Friday? As it is my only truly open time where I would not have to move another meeting. Or 5pm on Thursday?

Sorry, crazy schedule this week.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: b6 Mobile: b6

From: Culp, Michelle (NIH/OD) [E] b6

Sent: Wednesday, May 20, 2020 3:26 PM

To: Santos, Michael (FNIH) [T] b6 ; Tountas, Karen (FNIH) [T] b6 Adam, Stacey (FNIH) [T] <b6>

Cc: Tolman, Brett b6 >

Subject: RE: ACTIV Introduction

Good idea. I'm available Thursday from 3:00-4:30 and Friday is wide open.

-Michelle

From: Santos, Michael (FNIH) [T] b6

Sent: Wednesday, May 20, 2020 3:23 PM

To: Tountas, Karen (FNIH) [T] b6 , Adam, Stacey (FNIH) [T] b6 ; Culp, Michelle (NIH/OD) [E] <m b6>

Cc: Tolman, Brett b6 >

Subject: RE: ACTIV Introduction

I'd be happy to meet together.

As an FYI to Karen and Stacey, Brett and I set up a meeting with Michelle and Ellen tomorrow at 8am to go over an intro to what's happening in Vaccines and where we're headed. I'm guessing logistically this meeting will end up happening after that one, which would be ideal for our sequencing.

Thanks,

Mike

Michael Santos, PhD

Associate Vice President, Science Foundation for the National Institutes of Health

From: Tountas, Karen (FNIH) [T] b6

Sent: Wednesday, May 20, 2020 3:00 PM

To: Adam, Stacey (FNIH) [T] b6 >; Culp, Michelle (NIH/OD) [E] b6 Santos, Michael (FNIH) [T] <b6>

Subject: RE: ACTIV Introduction

All --

It might be most efficient to meet all together, especially since there will be increased interactions between the working group that I facilitate and the others.

My 2 cents worth...

Karen

From: Adam, Stacey (FNIH) [T] b6

Sent: Wednesday, May 20, 2020 2:28 PM

GADB0000003934

To: Culp, Michelle (NIH/OD) [E] <[REDACTED] b6> Santos, Michael (FNIH) [T] [REDACTED] b6 Tountas, Karen (FNIH) [T] <[REDACTED] b6>
Subject: RE: ACTIV Introduction

Hi Michelle,

I would be happy to meet to go over what is going on in my WG. I am happy to try and find a time for the group on our calendars if Mike and Karen would like.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 Mobile: ([REDACTED] b6)

From: Culp, Michelle (NIH/OD) [E] [REDACTED] b6
Sent: Wednesday, May 20, 2020 10:48 AM
To: Adam, Stacey (FNIH) [T] [REDACTED] b6 >; Santos, Michael (FNIH) [T] [REDACTED] b6 >; Tountas, Karen (FNIH) [T] [REDACTED] b6
Subject: ACTIV Introduction

Dear Stacey, Mike and Karen,
It was nice meeting you this morning on WebEx. I'm ready to get started and help where needed. I'll listen to the ACTIV Exec Comm meeting this afternoon to learn more about status of activities.

I'd like to have a brief call with for you to learn how I can help advise, influence or wrangle to move things ahead. It sounds like your calendars are busy. My calendar is still relatively open and flexible. If you think a call would be helpful, please feel free to suggest a time or just go ahead and add a time to my calendar.

All the best,
Michelle

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/11/2020 8:14:05 PM
To: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Subject: Accepted: ACTIV EC Pre-call
Location: see webex below
Start: 8/12/2020 4:00:00 PM
End: 8/12/2020 4:30:00 PM
Recurrence: {none}

From: Hallett, Adrienne (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F1705E2E7C254B84A77F058DBF75831B-HALLETAA]
Sent: 12/17/2020 12:49:31 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: Ivermectin

Thanks.

It's pretty clear the manufacturers are making the rounds. We're getting a few questions about ivermectin and some additional questions about the treatment guidelines that make me suspect the company would like to skip additional studies and go right to standard of care.

On Dec 17, 2020, at 5:25 AM, Collins, Francis (NIH/OD) [E] <[REDACTED]> wrote:

FYI regarding Senator Johnson's favorite drug.

From: Wholley, David (FNIH) [T] <[REDACTED]>
Sent: Wednesday, December 16, 2020 11:05 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]>
Subject: FW: Ivermectin

Hi Francis:

Please see below. Bottom line is that the expert scientific panel we have assembled is not sufficiently impressed with the data on ivermectin to bring it into ACTIV, and also note sufficient ongoing studies elsewhere, whose results they would like to see (among other data) before making testing of this agent a USG priority through ACTIV. Thanks, David

From: Adam, Stacey (FNIH) [T] <[REDACTED]>
Sent: Wednesday, December 16, 2020 7:28 PM
To: Wholley, David (FNIH) [T] <[REDACTED]>
Cc: Freire, Maria (FNIH) [T] <[REDACTED]>
Subject: RE: Ivermectin

Hi David,

As promised, here is the APC's decision on Ivermectin.

The APC has decided to "defer" the agent for further evaluation later by the committee. To trigger this reassessment, the APC is waiting on:

- Read out from at least 1-2 of the existing trials being conducted at UPenn, the EU (Gates Supported), and Japan.
- Preclinical data being generated by the NIAID team in their hamster models for further validation of antiviral efficacy.

Please let me know if you need further information.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6

Sent: Wednesday, December 16, 2020 6:54 AM

To: Wholley, David (FNIH) [T] [REDACTED] b6 >; Adam, Stacey (FNIH) [T] <[REDACTED] b6>; Parker, Ashley (NIH/OD) [E] <[REDACTED] b6>

Cc: Hallett, Adrienne (NIH/OD) [E] [REDACTED] b6

Subject: Ivermectin

Anything new in the prioritization re-review of ivermectin? Getting some pressure from a couple of Senators....

From: Hudson, Thomas J [REDACTED] b6
Sent: 4/16/2020 1:49:39 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: RE: URGENT: Need to know how to reach your comms contacts
Flag: Follow up

THIS IS THE CONTACT PERSON FOR ABBVIE.

JACKIE PACELLI (formerly Finley)
Senior Director
R&D Communications Global Grants and Donations

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THOMAS HUDSON
Senior Vice-President, R&D
Chief Scientific Officer

AbbVie, North Chicago

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N Chicago, IL 60064

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From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, April 16, 2020 5:28 AM
To: Hudson, Thomas J <[REDACTED]> b6 [REDACTED] b6 [REDACTED] b6
Cc: Myles, Renate (NIH/OD) [E] <[REDACTED]> b6 Meltzer, Abbey (FNIH) [T] <[REDACTED]> b6
Subject: [EXTERNAL] URGENT: Need to know how to reach your comms contacts
Importance: High

Hi Tom, William, and Amanda,

Can you provide comms contacts this morning? We are trying to post this press release later today.

COLL0000022388

Many thanks, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, April 16, 2020 8:13 AM

To: [REDACTED] b6

Cc: Myles, Renate (NIH/OD) [E] [REDACTED] b6 ; Parker, Ashley (NIH/OD) [E] <[REDACTED] b6> Burklow, John (NIH/OD) [E] [REDACTED] b6 >; Wholley, David (FNIH) [T] [REDACTED] b6 ; Meltzer, Abbey (FNIH) [T] <[REDACTED] b6>

Subject: Need to know how to reach your comms contacts

Importance: High

Dear ACTIV colleagues (once again, that's you in the bcc line):

As I mentioned yesterday, we would like to announce the plans for the ACTIV public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at [REDACTED] b6 and Abbey Meltzer [REDACTED] b6 as soon as possible.

Many thanks, Francis

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C18522-MYLESR]
Sent: 4/16/2020 12:41:22 PM
To: Pao, William b6 Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: RE: URGENT: Need to know how to reach your comms contacts

Flag: Follow up

Hi William:

We plan to issue the release today. Is there someone else on your team who is able to review the release?

Thanks,
Renate

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications, Public and
National Institutes of Health
Tel: b6

From: Pao, William <william.b6>
Sent: Thursday, April 16, 2020 8:38 AM
To: Collins, Francis (NIH/OD) [E] <b6>
Cc: Myles, Renate (NIH/OD) [E] <b6> Meltzer, Abbey (FNIH) [T] <b6>
Subject: RE: URGENT: Need to know how to reach your comms contacts

Dear Francis,
I just talked to Barbara Schaedler, our head of comms.
They are managing an activity today and she asked me to say that she can call you tomorrow but not today.
Her email is: b6 but she cannot respond today.
Best,
William

From: Collins, Francis (NIH/OD) [E] b6 >
Sent: 16 April 2020 14:28
To: b6
Cc: Myles, Renate (NIH/OD) [E] b6 >; Meltzer, Abbey (FNIH) [T] b6
Subject: URGENT: Need to know how to reach your comms contacts
Importance: High

Hi Tom, William, and Amanda,

Can you provide comms contacts this morning? We are trying to post this press release later today.

Many thanks, Francis

COLL0000022450

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, April 16, 2020 8:13 AM

To: [REDACTED] b6

Cc: Myles, Renate (NIH/OD) [E] [REDACTED] b6 Parker, Ashley (NIH/OD) [E] [REDACTED] b6 >; Burklow, John (NIH/OD) [E] [REDACTED] b6 Wholley, David (FNIH) [T] < [REDACTED] b6 Meltzer, Abbey (FNIH) [T] [REDACTED] b6

Subject: Need to know how to reach your comms contacts

Importance: High

Dear ACTIV colleagues (once again, that's you in the bcc line):

As I mentioned yesterday, we would like to announce the plans for the ACTIV public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at [REDACTED] b6 and Abbey Meltzer [REDACTED] b6) as soon as possible.

Many thanks, Francis

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C18522-MYLESR]
Sent: 4/16/2020 12:58:45 PM
To: Pao, William [b6]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-coilinsf]; Schaedler, Barbara [ba [b6]
CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: RE: URGENT: Need to know how to reach your comms contacts
Flag: Follow up

Thanks so much.

Barbara: I'll forward the email that went to other organizations this morning.

From: Pao, William <[b6]>
Sent: Thursday, April 16, 2020 8:57 AM
To: Myles, Renate (NIH/OD) [E] <[b6]>; Collins, Francis (NIH/OD) [E] <[b6]>; Schaedler, Barbara <[b6]>
Cc: Meltzer, Abbey (FNIH) [T] <[b6]>
Subject: RE: URGENT: Need to know how to reach your comms contacts

Dear Renate,
I'm cc'g Barbara who may be able to triage it to someone on her team.
Best,
William

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: 16 April 2020 14:41
To: Pao, William [b6] >; Collins, Francis (NIH/OD) [E] [b6] >
Cc: Meltzer, Abbey (FNIH) [T] [b6]
Subject: RE: URGENT: Need to know how to reach your comms contacts

Hi William:

We plan to issue the release today. Is there someone else on your team who is able to review the release?

Thanks,
Renate

Renate Myles, MSA
Deputy Director for Public Affairs
Office of Communications and Public Affairs
National Institutes of Health
[b6]

From: Collins, Francis (NIH/OD) [E] <[b6]>
Sent: 16 April 2020 14:28
To: [b6] [b6] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6] >; Meltzer, Abbey (FNIH) [T] [b6]

COLL0000022495

Subject: URGENT: Need to know how to reach your comms contacts
Importance: High

Hi Tom, William, and Amanda,

Can you provide comms contacts this morning? We are trying to post this press release later today.

Many thanks, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, April 16, 2020 8:13 AM

To: b6

Cc: Myles, Renate (NIH/OD) [E] <b6> Parker, Ashley (NIH/OD) [E] <b6> Burklow, John (NIH/OD) [E] <b6> Wholley, David (FNIH) [T] <b6> Meltzer, Abbey (FNIH) [T] <b6>

Subject: Need to know how to reach your comms contacts

Importance: High

Dear ACTIV colleagues (once again, that's you in the bcc line):

As I mentioned yesterday, we would like to announce the plans for the ACTIV public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at b6 and Abbey Meltzer b6) as soon as possible.

Many thanks, Francis

From: Burklow, John (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E57F267323B43C08BE856ACB5B964CA-BURKLOWJ]
Sent: 4/15/2020 1:33:27 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Re: Washington Post
Flag: Follow up

Yep. Renate now

Sent from my iPhone

On Apr 15, 2020, at 9:32 AM, Collins, Francis (NIH/OD) [E] <[REDACTED]> wrote:

I'm definitely not the leader -- can one of you do that?

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 9:32 AM
To: Burklow, John (NIH/OD) [E] <[REDACTED]> Myles, Renate (NIH/OD) [E] <[REDACTED]>
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]>
Subject: RE: Washington Post

I'm on the line waiting with music

From: Burklow, John (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, April 15, 2020 9:30 AM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]>
Cc: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Wood, Gretchen (NIH/OD) [E] <[REDACTED]>
Subject: Re: Washington Post

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Sent from my iPhone

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To: Collins, Francis (NIH/OD) [E] <[REDACTED]>

Cc: Myles, Renate (NIH/OD) [E]

b6

Wood, Gretchen (NIH/OD) [E]

b6

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Renate is speaking to the SDs right now about the OVP process, but will be finished soon. Will let you know.

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b6

> wrote:

Can we do a pre-call about this? Maybe at 9:30 AM on this same OCPL line?

FC

From: McManus, Ayanna (NIH/OD) [E]

b6

>

Sent: Wednesday, April 15, 2020 8:57 AM

To: Myles, Renate (NIH/OD) [E] <

b6

; Wood,

Gretchen (NIH/OD) [E]

b6

>

Cc: Collins, Francis (NIH/OD) [E]

b6

>; Burklow, John

(NIH/OD) [E]

b6

Subject: RE: Washington Post

Got it, thanks.

From: Myles, Renate (NIH/OD) [E]

b6

>

Sent: Wednesday, April 15, 2020 8:56 AM

To: McManus, Ayanna (NIH/OD) [E] <

b6

Wood, Gretchen (NIH/OD) [E] <

b6

Cc: Collins, Francis (NIH/OD) [E]

b6

>; Burklow, John

(NIH/OD) [E]

b6

Subject: FW: Washington Post

Hi Ayanna.

We can use the OCPL 2nd conference line;

b6

Participant Code:

b6

Leader Code: b6 (OCPL will activate)

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]

Sent: Wednesday, April 15, 2020 8:55 AM

To: McManus, Ayanna (NIH/OD) [E] <

b6

;

COLL0000018325

Wood, Gretchen (NIH/OD) [E] b6
Cc: Collins, Francis (NIH/OD) [E] b6 ; Burklow, John
(NIH/OD) [E] < b6 H.GOV>; Tabak, Lawrence (NIH/OD) [E]
b6 >; Lane, Cliff (NIH/NIAID) [E]
b6 Parker, Ashley (NIH/OD) [E]
b6 >; Wholley, David (FNIH) [T]
b6 Freire, Maria (FNIH) [T] < b6
Subject: RE: Washington Post

Thanks, Ayanna Carolyn has confirmed for 10.00 a.m. today.

From: McManus, Ayanna (NIH/OD) [E] b6
Sent: Wednesday, April 15, 2020 8:45 AM
To: Myles, Renate (NIH/OD) [E] b6 >; Wood,
Gretchen (NIH/OD) [E] b6
Cc: Collins, Francis (NIH/OD) [E] b6 Burklow, John
(NIH/OD) [E] b6 >; Tabak, Lawrence (NIH/OD) [E]
b6 >; Lane, Cliff (NIH/NIAID) [E]
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b6 Wholley, David (FNIH) [T]
b6 >; Freire, Maria (FNIH) [T] < b6
Subject: RE: Washington Post

Renate,

Jumping In for Gretchen. FC is available anytime between 9:15 and 11 AM.

Thanks,
Ayanna

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Sent: Wednesday, April 15, 2020 8:42 AM
To: Wood, Gretchen (NIH/OD) [E] < b6 .
Cc: Collins, Francis (NIH/OD) [E] b6 >; Burklow, John
(NIH/OD) [E] b6 >; Tabak, Lawrence (NIH/OD) [E]
b6 : Lane, Cliff (NIH/NIAID) [E]
< b6 Parker, Ashley (NIH/OD) [E]
< b6 : Wholley, David (FNIH) [T]
b6 >; Freire, Maria (FNIH) [T] b6
McManus, Ayanna (NIH/OD) [E] b6 >
Subject: RE: Washington Post

Okay, thanks. MS 360 update seems to have gotten everyone.

Francis: I'm about to send you a compilation of Carolyn's questions and what Cliff/Tony provided. Just let me know when you're available.

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To: Myles, Renate (NIH/OD) [E] b6
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McManus, Ayanna (NIH/OD) [E] b6 >
Subject: Re: Washington Post

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Burklow, John (NIH/OD) [E] < b6 >;
Tabak, Lawrence (NIH/OD) [E] b6 >; Lane, Cliff (NIH/NIAID) [E] < b6 >
Cc: Wood, Gretchen (NIH/OD) [E] < b6 > Parker, Ashley (NIH/OD) [E] b6 >; Wholley, David (FNIH) [T] b6 >; Freire, Maria (FNIH) [T] b6
McManus, Ayanna (NIH/OD) [E] b6
Subject: RE: Washington Post

Yes, definitely!!! My message to you got caught in the Outlook reboot last night, so when I said "tomorrow" I meant today!

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To: Collins, Francis (NIH/OD) [E] < b6 >
Burklow, John (NIH/OD) [E] b6 ;
Tabak, Lawrence (NIH/OD) [E] < b6 > Lane, Cliff (NIH/NIAID) [E]

b6

Cc: Wood, Gretchen (NIH/OD) [E]

< b6 , Parker, Ashley (NIH/OD) [E]

b6 >; Wholley, David (FNIH) [T]

< b6 >; Freire, Maria (FNIH) [T]

< b6

Subject: RE: Washington Post

Hi Francis:

Any chance you can speak to Carolyn by end of day today? She's pushing for comment today.

Renate

From: Collins, Francis (NIH/OD) [E]

< b6

Sent: Wednesday, April 15, 2020 4:04 AM

To: Myles, Renate (NIH/OD) [E] b6

Burklow, John (NIH/OD) [E] b6 ;

Tabak, Lawrence (NIH/OD) [E]

< b6 Lane, Cliff (NIH/NIAID) [E]

< b6

Cc: Wood, Gretchen (NIH/OD) [E]

< b6 , Parker, Ashley (NIH/OD) [E]

b6 >; Wholley, David (FNIH) [T]

b6 Freire, Maria (FNIH) [T]

< b6

Subject: FW: Washington Post

Hi all,

As you can see from Tony's message, he got a green light from WH Comms (Devin O'Malley) for me to talk with Carolyn Johnson tomorrow about ACTIV. Apparently there was no time to discuss this with the Task Force today (they were all focused on economics) but Tony was able to talk with Comms – b5

b5

b5

Tony

called me earlier in the evening to make sure that wasn't the case, and I reassured him. Given that, the WH Comms said it was OK to talk with Carolyn,

b5

b5

b5

b5

b5

b5

b5

Renate, can you work with Gretchen to find a good time for me to talk with Carolyn tomorrow?

I'll need to send out that note to ACTIV partners to let them know a press story is coming. That would include industry, academics, and other government participants. I'm ccing Ashley to ask her to work with David Wholley and his team to get me a complete e-mail list. As you know, Dolsten has agreed to be a press contact. No word back yet from Stoffels.

FC

From: Fauci, Anthony (NIH/NIAID) [E]

b6

>

Sent: Tuesday, April 14, 2020 9:44 PM

To: Johnson, Carolyn

[<Carolyn.Johnson@washpost.com>](mailto:Carolyn.Johnson@washpost.com)

Cc: Collins, Francis (NIH/OD) [E]

b6

Lane, Cliff (NIH/NIAID) [E]

b6

; Billet,

Courtney (NIH/NIAID) [E]

b6

;

Conrad, Patricia (NIH/NIAID) [E]

b6

Subject: RE: Washington Post

Carolyn:

Thanks for the note. I understand that you will be hearing from Francis Collins on the Public Private Partnership (PPP) that we have put together to combine the resources and assets of industry and the academic community that is largely supported by NIH, particularly NIAID in the context of COVID-19. It is the functional equivalent of a National Strategy. We at NIAID and to some extent other institutes are leveraging our vast clinical trials networks that we built for other infectious diseases, particularly, but not exclusively HIV/AIDS, to provide the capacity to conduct clinical trials (NIH-sponsored as well as industry-sponsored) for both vaccines and therapeutics for COVID-19. For your interest, I am attaching a copy (not yet released) of the NIAID Strategic Plan for COVID-19 Research. It is an outline that will be supplemented with an implementation plan.

COLL0000018325

Best regards,
Tony

From: Johnson, Carolyn
<Carolyn.Johnson@washpost.com>
Sent: Tuesday, April 14, 2020 10:23 AM
To: Fauci, Anthony (NIH/NIAID) [E]
b6 >
Subject: Washington Post

Dear Tony,
Is there a national strategy at the task force level to coordinate clinical research efforts nationally? We have heard lots of complaints that there isn't a national strategy. I talked to Cliff Lane about this, but we want to give you the chance to respond.
Carolyn

Carolyn Johnson
Washington Post
202-334-6248 (desk)
b6 (cell)

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C18522-MYLESR]
Sent: 4/15/2020 1:34:11 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: Washington Post
Flag: Follow up

I've activated it.

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Wednesday, April 15, 2020 9:33 AM
To: Burklow, John (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Myles, Renate (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Subject: RE: Washington Post

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Sent: Wednesday, April 15, 2020 9:32 AM
To: Burklow, John (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Myles, Renate (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Subject: RE: Washington Post

I'm on the line waiting with music

From: Burklow, John (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Wednesday, April 15, 2020 9:30 AM
To: Myles, Renate (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Wood, Gretchen (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
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Sent from my iPhone

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I'm off and am avai able now.

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< [REDACTED] b6

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Hi Ayanna:

We can use the OCPL 2nd conference line;

[REDACTED] b6
Participant Code: [REDACTED] b6
Leader Code: [REDACTED] b6 (OCPL will activate)

Thanks,
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Sent: Wednesday, April 15, 2020 8:55 AM
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COLL0000018328

(FNIH) [T] < [REDACTED] b6
Subject: RE: Washington Post

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COLL0000018328

<[REDACTED] b6 [REDACTED], Lane, Cliff (NIH/NIAID) [E]

[REDACTED] b6 [REDACTED]

Cc: Wood, Gretchen (NIH/OD) [E] [REDACTED] b6 [REDACTED] >; Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED] >; Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED] >; Freire, Maria (FNIH) [T] [REDACTED] b6 [REDACTED]

Subject: FW: Washington Post

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[REDACTED] b5 [REDACTED]

[REDACTED] b5 [REDACTED] Tony called me earlier in the evening to make sure that wasn't the case, and I reassured him. Given that, the WH Comms said it was OK to talk with Carolyn, [REDACTED] b5 [REDACTED]

[REDACTED] b5 [REDACTED]

[REDACTED] b5 [REDACTED]

[REDACTED] b5 [REDACTED]

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Sent: Tuesday, April 14, 2020 9:44 PM

To: Johnson, Carolyn <Carolyn.Johnson@washpost.com>

Cc: Collins, Francis (NIH/OD) [E] [REDACTED] b6 [REDACTED] >; Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 [REDACTED] >; Billet, Courtney (NIH/NIAID) [E] [REDACTED] b6 [REDACTED] >; Conrad, Patricia (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]

Subject: RE: Washington Post

Carolyn:

Thanks for the note. I understand that you will be hearing from Francis Collins on the Public Private Partnership (PPP) that we

COLL0000018328

have put together to combine the resources and assets of industry and the academic community that is largely supported by NIH, particularly NIAID in the context of COVID-19. It is the functional equivalent of a National Strategy. We at NIAID and to some extent other institutes are leveraging our vast clinical trials networks that we built for other infectious diseases, particularly, but not exclusively HIV/AIDS, to provide the capacity to conduct clinical trials (NIH-sponsored as well as industry-sponsored) for both vaccines and therapeutics for COVID-19. For your interest, I am attaching a copy (not yet released) of the NIAID Strategic Plan for COVID-19 Research. It is an outline that will be supplemented with an implementation plan.

Best regards,
Tony

From: Johnson, Carolyn <Carolyn.Johnson@washpost.com>
Sent: Tuesday, April 14, 2020 10:23 AM
To: Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]> **b6**
Subject: Washington Post

Dear Tony,
Is there a national strategy at the task force level to coordinate clinical research efforts nationally? We have heard lots of complaints that there isn't a national strategy. I talked to Cliff Lane about this, but we want to give you the chance to respond.
Carolyn

Carolyn Johnson
Washington Post
202-334-6248 (desk)
[REDACTED] **b6** (cell)

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 7/30/2020 9:44:31 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: CLOSE HOLD: Update on ACTIV Rollout Activities

And we'd love her to come in person if she can.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

b6

From: Myles, Renate (NIH/OD) [E] < > b6
Sent: Thursday, July 30, 2020 5:40:04 AM
To: Collins, Francis (NIH/OD) [E] < > b6
Subject: Re: CLOSE HOLD: Update on ACTIV Rollout Activities

Yes, that would be great. I'll also go through FDA comms channels. We're in touch with Eli Lilly. I'll note your recommendation.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

b6

From: Collins, Francis (NIH/OD) [E] < > b6
Sent: Wednesday, July 29, 2020 9:55:05 PM
To: Myles, Renate (NIH/OD) [E] < > b6
Subject: RE: CLOSE HOLD: Update on ACTIV Rollout Activities

Do you want me to ask Janet Woodcock about August 4? I think the Lilly rep should be Dan Skovronsky, but I guess you have to ask them.

FC

From: Myles, Renate (NIH/OD) [E] < > b6
Sent: Wednesday, July 29, 2020 5:41 PM
To: Collins, Francis (NIH/OD) [E] < > b6 Freire, Maria (FNIH) [T] < > b6 Wholley, David (FNIH) [T] < > b6 Adam, Stacey (FNIH) [T] < > b6
Cc: Burklow, John (NIH/OD) [E] < > b6 Fine, Amanda (NIH/OD) [E] < > b6
Wojtowicz, Emma (NIH/OD) [E] < > b6 Seigfreid, Kim (NIH/OD) [E] < > b6
Polimeni, Lydia (NIH/OD) [E] < > b6 Tabak, Lawrence (NIH/OD) [E] < > b6
Schwetz, Tara (NIH/OD) [E] < > b6 Wolinetz, Carrie (NIH/OD) [E] < > b6 Parker, Ashley (NIH/OD) [E] < > b6 Hallett, Adrienne (NIH/OD) [E] < > b6 Higgins, Lauren (NIH/OD) [E] < > b6 Meltzer, Abbey (FNIH) [T] < > b6 Gorman, Greta (FNIH) [T]

< b6

Subject: CLOSE HOLD: Update on ACTIV Rollout Activities

Good evening:

I wanted to give you an update on the ACTIV announcements next week. Below is the timing for announcing ACTIV-2, ACTIV-3, and ACTIV-4. These dates/time are pretty solid, but there is always a chance that something could change. I will share final releases once we have them. I also wanted to flag that we added a [Vaccines page](#) to the ACTIV website. Vaccine trials using the ACTIV-informed harmonized protocol will be added to this page. We also are working on Working Group pages (with help from Ashley Parker) and will circulate the content for those pages as soon as possible.

Tuesday, August 4:

ACTIV-2 Outpatient Monoclonal and ACTIV-3 Inpatient Monoclonal Announcements:

- Two separate release issued at the same time. One media telebriefing.

Building 1/151:

9:30 a.m.: Media Telebriefing Pre-call
10:00-11:00 a.m.: Media Telebriefing

Building 1/Wilson Hall

11:30-12:00 p.m.: Social Media Event

Participants in Media Telebriefing:

- NIH Director Francis Collins
- NIAID Director Anthony Fauci
- OWS Therapeutics Lead Janet Woodcock (need to make the ask)
- Eli Lilly Spokesperson (TBD)
- FNIH Senior Vice President of Research Partnerships David Wholley

Participants in Social Media Event:

- NIH Director Francis Collins
- NIAID Director Anthony Fauci

Thursday, August 6:

ACTIV-4 Antithrombotics Announcement:

Building 1/151:

10:00 a.m.: Media Telebriefing Pre-call
10:30-11:30 a.m.: Media Telebriefing

Building 1/Wilson Hall

Noon-12:30 p.m.: Social Media Event

Participants:

- NIH Director Francis Collins
- NHLBI Director Gary Gibbons

COLL0000016073

- FNIH Senior Vice President of Research Partnerships David Wholley

Thanks,
Renate

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/5/2020 2:44:31 AM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Data-Sharing

Nicely done. ☺ I suspect his face is a bit red right now.

-----Original Message-----

From: Freire, Maria (FNIH) [T] <[REDACTED]>
Sent: Thursday, June 4, 2020 10:42 PM
To: Plump, Andrew <[REDACTED]> Collins, Francis (NIH/OD) [E] <[REDACTED]> Paul Stoffel <[REDACTED]> Heatherington, Anne <[REDACTED]> Perala, Mie <[REDACTED]>
Cc: Mikael Dolsten MD PhD <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>
Subject: RE: Data-Sharing

Andy,

I will ask my Assistant, Dorina Sepulveda, to help set this up - unless you would like to have someone on your staff help do this, Francis.

Maria

Maria C. Freire, Ph.D.
President and Executive Director
Foundation for the National Institutes of Health
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
[REDACTED] fnih.org

-----Original Message-----

From: Plump, Andrew <Andrew.[REDACTED]>
Sent: Thursday, June 4, 2020 7:38 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Paul Stoffel <[REDACTED]> Heatherington, Anne <[REDACTED]> Perala, Mie <[REDACTED]>
Cc: Mikael Dolsten MD PhD <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>
Subject: RE: Data-Sharing

Hi Francis,

Thank you for the rapid and positive response.

Anne has really been leading this with her counterparts across industry. She will assemble the right group and we can find an hour over the next couple of weeks. In addition to a dive into the Gates' data architecture, she or someone from Transcelerate can overview the patient-level data platform.

Larry, if you have specific requests for the meeting please let Anne know directly.

Mie can work with Maria to identify participants help find an hour. Given the agendas in play, hopefully everyone can be a bit flexible and/or find time off hours.

Warm regards,
Andy

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew <[REDACTED]> Paul Stoffel <[REDACTED]> Heatherington, Anne <[REDACTED]>
Cc: Mikael Dolsten MD PhD <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>
Subject: RE: Data-Sharing

COLL0000020628

Be advised that this email came from outside Takeda / お知らせ 社外から送信されたメールです

Hi Andy,

Thanks for your leadership on these critical data sharing issues -- and yes, a group of us from NIH/FNIH would very much like to meet with you, Anne, and any others that you think would assist the conversation. I have already asked my principal Deputy, Dr. Larry Tabak, to assemble the right NIH group to take part in this conversation, and I will count on David to figure out who should attend from FNIH.

One of the items that I know the group will want to know more about is the Gates Accelerator -- it's been hard to get a sense of the architecture and ease of use. Is there a beta test model available that we could try out?

Best, Francis

-----Original Message-----

From: Plump, Andrew <[REDACTED]> b6
Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 ; Paul Stoffel <[REDACTED]> b6
Heatherington, Anne <[REDACTED]> b6
Cc: Mikael Dolsten MD PhD <[REDACTED]> b6 ; Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: Data-sharing

Hi Francis and Paul,

Terrific ACTIV leadership meeting yesterday. Remarkable progress.

Following up on the HEVER dialogue on data-sharing. I know you are fully on board with the need for essentially real-time data sharing of emerging clinical trial data, and there is a team that has identified a framework that should work for the NIH. While there may be arcane US government provisions to which we are not aware, the privacy considerations are at least as stringent within industry, and essentially all companies have agreed to the framework Anne presented, so I do not imagine roadblocks.

My suggestion is that Anne and members of the data-sharing group meet with you, David, and/or whomever else you would suggestion from NIH/ACTIV to bring you up to speed and figure out a path forward.

Thanks,
Andy

Sent from my iPad

The content of this email and of any files transmitted may contain confidential, proprietary or legally privileged information and is intended solely for the use of the person/s or entity/ies to whom it is addressed. If you have received this email in error you have no permission whatsoever to use, copy, disclose or forward all or any of its contents. Please immediately notify the sender and thereafter delete this email and any attachments.

COLL0000020628

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/15/2020 2:46:40 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: FW: Washington Post
Attachments: Master list for ACTIV.xlsx

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 10:41 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Francis,

Please see the attached email list. I think this can work for now but I have stressed to FNIH that this is not sufficient long term as the names of who these emails belong to are not listed. Cheryl will further refine but hopefully this will work for now.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 10:01 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6** >
Subject: RE: Washington Post

Yes this is correct. I also want to ensure that any late additions (reps from BMGF, others) are also captured – we should have the compiled list shortly.

Thanks for your patience – bad timing with 365 updates last night.

Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 9:57 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6** >
Subject: RE: Washington Post

Thanks. I'll wait for the single e-mail list that I can just copy into the bcc line – I assume that's what Cheryl is doing....

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 9:53 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Hi Francis,

We had a few issues this morning – the FNIH staffer could not open emails due to the 365 update which causes a severe delay.

Here's what just came in – I've asked Cheryl at FNIH to compile these into a single email list to avoid duplicates and she's doing this now (will have soon). But for the sake of time here are the emails.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 9:45 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Need these in the next 30 minutes – how is it coming?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 8:28 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**; Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**; Burklow, John (NIH/OD) [E] <[REDACTED]> **b6**; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Freire, Maria (FNIH) [T] <[REDACTED]> **b6**; McManus, Ayanna (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Good morning Francis et al.

I am working with David to compile the email list – we will send the list ASAP.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 8:10 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**; Burklow, John (NIH/OD) [E] <[REDACTED]> **b6**; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6**
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> **b6**; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Freire, Maria (FNIH) [T] <[REDACTED]> **b6**; McManus, Ayanna (NIH/OD) [E] <[REDACTED]> **b6**
Subject: RE: Washington Post

Okay; working it out.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Wednesday, April 15, 2020 8:02 AM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**; Burklow, John (NIH/OD) [E] <[REDACTED]> **b6**; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> **b6**; qv> **b6**
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> **b6**; Parker, Ashley (NIH/OD) [E] <[REDACTED]> **b6**; Wholley, David (FNIH) [T] <[REDACTED]> **b6**; Freire, Maria (FNIH) [T] <[REDACTED]> **b6**; McManus, Ayanna (NIH/OD) [E] <[REDACTED]> **b6**

(NIH/OD) [E] b6
Subject: RE: Washington Post

Yes, definitely!!! My message to you got caught in the Outlook reboot last night, so when I said "tomorrow" I meant today!

From: Myles, Renate (NIH/OD) [E] < b6
Sent: Wednesday, April 15, 2020 7:35 AM
To: Collins, Francis (NIH/OD) [E] b6 Burklow, John (NIH/OD) [E] b6 ; Tabak,
Lawrence (NIH/OD) [E] b6 >; Lane, Cliff (NIH/NIAID) [E] b6 >
Cc: Wood, Gretchen (NIH/OD) [E] b6 >; Parker, Ashley (NIH/OD) [E] b6
Wholey, David (FNIH) [T] b6 >; Freire, Maria (FNIH) [T] b6
Subject: RE: Washington Post

Hi Francis:

Any chance you can speak to Carolyn by end of day today? She's pushing for comment today.

Renate

From: Collins, Francis (NIH/OD) [E] b6
Sent: Wednesday, April 15, 2020 4:04 AM
To: Myles, Renate (NIH/OD) [E] b6 Burklow, John (NIH/OD) [E] b6 >; Tabak,
Lawrence (NIH/OD) [E] b6 ; Lane, Cliff (NIH/NIAID) [E] b6
Cc: Wood, Gretchen (NIH/OD) [E] b6 >; Parker, Ashley (NIH/OD) [E] < b6 >;
Wholey, David (FNIH) [T] < b6 Freire, Maria (FNIH) [T] b6 >
Subject: FW: Washington Post

Hi all,

As you can see from Tony's message, he got a green light from WH Comms (Devin O'Malley) for me to talk with Carolyn Johnson tomorrow about ACTIV. Apparently there was no time to discuss this with the Task Force today (they were a l focused on economics) but Tony was able to talk with Comms – b5

b5 Tony called me earlier in the evening to make sure that wasn't the case, and I reassured him. Given that, the WH Comms said it was OK to talk with Carolyn, b5

b5

b5

Renate, can you work with Gretchen to find a good time for me to talk with Carolyn tomorrow?

I'll need to send out that note to ACTIV partners to let them know a press story is coming. That would include industry, academics, and other government participants. I'm ccing Ashley to ask her to work with David Wholey and his team to get me a complete e-mail list. As you know, Dolsten has agreed to be a press contact. No word back yet from Stoffels.

FC

COLL0000020922

From: Fauci, Anthony (NIH/NIAID) [E] b6
Sent: Tuesday, April 14, 2020 9:44 PM
To: Johnson, Carolyn < > b6
Cc: Collins, Francis (NIH/OD) [E] b6 >; Lane, Cliff (NIH/NIAID) [E] b6 ; Billet, Courtney (NIH/NIAID) [E] b6 ; Conrad, Patricia (NIH/NIAID) [E] b6
Subject: RE: Washington Post

Carolyn:

Thanks for the note. I understand that you will be hearing from Francis Collins on the Public Private Partnership (PPP) that we have put together to combine the resources and assets of industry and the academic community that is largely supported by NIH, particularly NIAID in the context of COVID-19. It is the functional equivalent of a National Strategy. We at NIAID and to some extent other institutes are leveraging our vast clinical trials networks that we built for other infectious diseases, particularly, but not exclusively HIV/AIDS, to provide the capacity to conduct clinical trials (NIH-sponsored as well as industry-sponsored) for both vaccines and therapeutics for COVID-19. For your interest, I am attaching a copy (not yet released) of the NIAID Strategic Plan for COVID-19 Research. It is an outline that will be supplemented with an implementation plan.

Best regards,

Tony

From: Johnson, Carolyn <Carolyn.Johnson@washpost.com>
Sent: Tuesday, April 14, 2020 10:23 AM
To: Fauci, Anthony (NIH/NIAID) [E] b6 >
Subject: Washington Post

Dear Tony,

Is there a national strategy at the task force level to coordinate clinical research efforts nationally? We have heard lots of complaints that there isn't a national strategy. I talked to Cliff Lane about this, but we want to give you the chance to respond.

Carolyn

Carolyn Johnson
Washington Post
202-334-6248 (desk)
b6 (cell)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/18/2020 9:08:58 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: ACTIV 2 and 3 trial activation and enrollment

Should you invite Janet and Stacey to war room tomorrow at 8 so we can discuss this head on? ...given the urgency.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, August 18, 2020 3:47 PM
To: Woodcock, Janet (FDA/CDER) <[REDACTED]> Tabak, Lawrence (NIH/OD) [E]
<[REDACTED]> Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E]
<[REDACTED]>
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Freire, Maria (FNIH) [T]
<[REDACTED]> Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> Anderson, James (NIH/OD) [E]
<[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: RE: ACTIV 2 and 3 trial activation and enrollment

Hi Janet,

Thanks for your note. I agree completely that these challenges with recruitment to ACTIV-2 need to be tackled head on. I'm looping in Stacey Adam and the other members of the ACTIV War Room to see what other suggestions they might have. I am happy to call anyone anytime if it would help to convey the sense of urgency and high priority.

Francis

From: Woodcock, Janet <[REDACTED]>
Sent: Tuesday, August 18, 2020 12:55 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]> >; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>
Subject: ACTIV 2 and 3 trial activation and enrollment

After heroic efforts by all involved to get these studies up and running, we now face the issue of continuing the momentum. ACTIV 2 has not yet enrolled the first patient. ACTIV 3 has been "going slow" since there was limited safety data on the antibody, but after 27 infusions and no SAEs, they will continue to enroll and have a DSMB look at the safety data on Aug 31. At that point, they should be poised to enroll very quickly. As you know, it is possible there will be a convalescent plasma EUA and that could detract from enrollment in this study, as will the HIG RCT being done by INSIGHT. The main bottleneck will be study personnel bandwidth, not patient availability.

Diagnostics have been done on ACTIV 2 and some solutions are being put into place. Site activation is problematic and the CRO needs to step up. The OWS leadership has offered to bring in freestanding trailers that can be used for infusions and visits, since despite Francis's email about the urgency space is still begrudged at some of the sites, and at some it's just not available. Rapid diagnostics have been obtained.

ACTIV 3 has an ambitious plan to bring on more sites in the upcoming weeks. The remdesivir issue is resolving.

Nevertheless the formal projections of milestones for these studies stretch way into the new year. We need evaluation much faster if we are to impact this outbreak.

I propose that the NIH leadership work with OWS (me and others) to develop some realistic but aggressive goals and timelines to negotiate with the study teams. I recognize that everyone is burdened but this needs to be made a priority and any support needed should be surfaced and provided. Please let me know what you collectively think about this.

jw

From: Denny, Joshua (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CDB4626DABBB45AA8B8E5D21169344E6-DENNYJC]
Sent: 5/18/2020 10:24:13 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fct28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Reid, Nancy (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=baa8b238107d4c39822dbe4459ff0089-reidnc]; Gebo, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=009cf99ae63f4f71b5b1204a73ded609-geboka]
Subject: Re: All of Us program and vaccine trials?

Hi Karen,

Thanks for the quick reply! I'd be more than happy to talk about this, and I can make either of these times work. I'm also copying our chief medical/science officer, Kelly Gebo.

If you have a list of sites you have identified for the site inventory, we could also easily look for direct overlaps before we meet as well.

Best,

Josh

On May 18, 2020, at 6:13 PM, Tountas, Karen (FNIH) [T] <[REDACTED]> wrote:

Dear Francis,

Your email is very timely. The Clinical Trial Capacity Working Group (CTC WG) had very briefly brought up the ALL of Us program very early in their discussions, but had, at that time, focused intently on generating a CRO SMO/Network/Site inventory for therapeutics. And, now, vaccines trials are on the horizon so...

Josh - It would be very interesting to the CTC WG members to hear about the program and to explore with you how ACTIV might harness its potential for vaccine trials. Would you have time to talk with the WG? We meet on Tuesdays and Fridays at 9 am via Zoom. Would this Friday, May 22, or next Tuesday, May 26, work for you? Many thanks for considering this opportunity.

Cheers!

Karen

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Monday, May 18, 2020 5:59 PM
To: Wholley, David (FNIH) [T] [REDACTED] b6; Tountas, Karen (FNIH) [T] [REDACTED] b6
Adam, Stacey (FNIH) [T] [REDACTED] b6
Cc: Denny, Joshua (NIH/OD) [E] [REDACTED] b6
Subject: All of Us program and vaccine trials?

Hi David, Karen, and Stacey,

A couple of weeks ago I brought up the idea of exploring the possibility of enlisting the *All of Us* program as a source of volunteers for COVID-19 vaccine trials. With ~240,000 motivated and highly diverse participants, pre-consented for recontact, and located all over the country including areas where COVID-19 is actively spreading, this seems like an interesting opportunity. And there are repository biospecimens available for them too.

Did that discussion go anywhere? Josh Denny (cc'd here), the CEO of *All of Us*, would be glad to engage with you about specifics if that would help.

Francis

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 6/5/2020 2:53:05 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf], Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: Data-Sharing

Thanks for doing this Gretchen. Unless Francis or Larry feel otherwise. I don't really need to be included in this discussion. So one less crazy schedule to deal with! Best, M.

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Thursday, June 4, 2020 at 10:47:14 PM
To: "Wood, Gretchen (NIH/OD) [E]" <[REDACTED]> **b6**
Cc: "Freire, Maria (FNIH) [T]" <[REDACTED]> **b6**, "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> **b6**, "Wholley, David (FNIH) [T]" <[REDACTED]> **b6**
Subject: FW: Data-Sharing

Hey Gretchen,

I have a challenge for your able skills. We need a 45 minute WebEx with Andy Plump and Anne Heatherington of Takeda (work with Mie), and a whole bunch of folks (including me) from NIH and FNIH – as you can see from the e-mail thread below. Can you try to make this happen some time next week?

FC

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Thursday, June 4, 2020 10:43 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> **b6**, Freire, Maria (FNIH) [T] <[REDACTED]> **b6**, Wholley, David (FNIH) [T] <[REDACTED]> **b6**
Subject: Re: Data-Sharing

Yes please!

From the NIH side – Chris has asked to join; he wants Mike Kurilla
David recommended Ellen Gadbois and Michele Culp join and I think that is an excellent idea.
We should also include Patti Brennan, Jerry Sheehan, and Susan Gregurick. If available I would also include Andrea Norris.

Thanks
Larry

From: Francis Collins <[REDACTED]> **b6**
Date: Thursday, June 4, 2020 at 10:15 PM

To: "Freire, Maria (FNIH) [T]" <[REDACTED] b6 [REDACTED]>, "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED]>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Subject: RE: Data-Sharing

He obviously doesn't know who he's dealing with!

Larry, shall I offer Gretchen or Ayanna to help with the logistics?

FC

From: Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Sent: Thursday, June 4, 2020 7:46 PM
To: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>, Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Subject: Fwd: Data-Sharing

Maria (the secretary) will set this up?! Is he kidding me?!!

From: "Plump, Andrew" <[REDACTED] b6 [REDACTED]>
Date: Thursday, June 4, 2020 at 7:38:20 PM
To: "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Paul Stoffel" <[REDACTED] b6 [REDACTED]>, "Heatherington, Anne" <[REDACTED] b6 [REDACTED]>, "Perala, Mic" <[REDACTED] b6 [REDACTED]>
Cc: "Mikael Dolsten MD PhD" <[REDACTED] b6 [REDACTED]>, "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED]>, "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Freire, Maria (FNIH) [T]" <[REDACTED] b6 [REDACTED]>, "Austin, Christopher (NIH/NCATS) [E]" <[REDACTED] b6 [REDACTED]>
Subject: RE: Data-Sharing

Hi Francis,

Thank you for the rapid and positive response.

Anne has really been leading this with her counterparts across industry. She will assemble the right group and we can find an hour over the next couple of weeks. In addition to a dive into the Jakes' data architecture, she or someone from Transcelerate can overview the patient level data platform.

Larry, if you have specific requests for the meeting please let Anne know directly.

Mic can work with Maria to identify participants help find an hour. Given the agendas in play, hopefully everyone can be a bit flexible and/or find time off hours.

Warm regards,
Andy

-----Original Message-----

COLL0000017509

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew [REDACTED] b6 >; Paul Stoffel [REDACTED] b6 Heatherington, Anne [REDACTED] b6 >
Cc: Mikael Dolsten MD PhD [REDACTED] b6 >; Wholley, David (FNIH) [T] [REDACTED] b6 >; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 >; Freire, Maria (FNIH) [T] [REDACTED] b6 Austin, Christopher (NIH/NCATS) [E] <[REDACTED] b6>
Subject: RE: Data-Sharing

Be advised that this email came from outside Takeda / お知らせ: 社外から送信されたメールです

Hi Andy,

Thanks for your leadership on these critical data sharing issues -- and yes, a group of us from NIH/FNIH would very much like to meet with you, Anne, and any others that you think would assist the conversation. I have already asked my principal Deputy, Dr. Larry Tabak, to assemble the right NIH group to take part in this conversation, and I will count on David to figure out who should attend from FNIH.

One of the items that I know the group will want to know more about is the Gates Accelerator -- it's been hard to get a sense of the architecture and ease of use. Is there a beta test mode available that we could try out?

Best, Francis

-----Original Message-----

From: Plump, Andrew <[REDACTED] b6>
Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>; Paul Stoffel [REDACTED] b6 >; Heatherington, Anne [REDACTED] b6 >
Cc: Mikael Dolsten MD PhD [REDACTED] b6 >; Wholley, David (FNIH) [T] <[REDACTED] b6>
Subject: Data-Sharing

Hi Francis and Paul,

Terrific ACTIV leadership meeting yesterday. Remarkable progress.

Following up on the HIVER dialogue on data sharing. I know you are fully on board with the need for essentially real time data sharing of emerging clinical trial data, and there is a team that has identified a framework that should work for the NIH. While there may be arcane US government provisions to which we are not aware, the privacy considerations are at least as stringent within industry, and essentially all companies have agreed to the framework Anne presented, so I do not imagine roadblocks.

My suggestion is that Anne and members of the data-sharing group meet with you, David, and/or whomever else you would suggest from NIH/ACTIV to bring you up to speed and figure out a path forward.

COLL0000017509

Thanks,
Andy

Sent from my iPad

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From: Perala, Mie [b6]
Sent: 6/5/2020 8:59:20 PM
To: Heatherington, Anne [b6] Plump, Andrew [b6] Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Paul Stoffel [b6]
CC: Mikael Dolsten MD PhD [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Kolligian, Andrea [b6] Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: Data-Sharing
Flag: Follow up

Hi Anne,

Gretchen has been kindly taking care of the scheduling and I had shared two possible slots with Andrea.

Thanks,
Mie

-----Original Message-----

From: Heatherington, Anne [b6]
Sent: Friday, June 5, 2020 4:26 PM
To: Plump, Andrew [b6] Collins, Francis (NIH/OD) [E] [b6] Paul Stoffel [b6] Perala, Mie [b6]
Cc: Mikael Dolsten MD PhD [b6] Wholley, David (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6] Freire, Maria (FNIH) [T] <mfreire@fnih.org>; Austin, Christopher (NIH/NCATS) [E] [b6]
Subject: RE: Data-Sharing

I am really happy to co-ordinate this discussion. I note the request for a deeper understanding of the Gates Accelerator - as Andy said, do you have other specific requests and I can make sure the answers are provided.

I would plan to include representatives from TransCelerate, Gates Foundation and maybe 2 other pharma for balance.

Anne

-----Original Message-----

From: Plump, Andrew [b6]
Sent: Thursday, June 4, 2020 7:38 PM
To: Collins, Francis (NIH/OD) [E] [b6] Paul Stoffel [b6] Heatherington, Anne <anne.heathe [b6] Perala, Mie [b6]
Cc: Mikael Dolsten MD PhD [b6] Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] [b6] Freire, Maria (FNIH) [T] [b6] Austin, Christopher (NIH/NCATS) [E] [b6]
Subject: RE: Data-Sharing

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Larry, if you have specific requests for the meeting please let Anne know directly.

Mie can work with Maria to identify participants help find an hour. Given the agendas in play, hopefully everyone can be a bit flexible and/or find time off hours.

COLL0000017538

warm regards,
Andy

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Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew <[REDACTED] b6 [REDACTED]> Paul Stoffel <[REDACTED] b6 [REDACTED]> Heatherington, Anne
<[REDACTED] b6 [REDACTED]>
Cc: Mikael Dolsten MD PhD <[REDACTED] b6 [REDACTED]> Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 [REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]>
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Best, Francis

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To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]> Paul Stoffel <[REDACTED] b6 [REDACTED]>
Heatherington, Anne <[REDACTED] b6 [REDACTED]>
Cc: Mikael Dolsten MD PhD <[REDACTED] b6 [REDACTED]> Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>
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COLL0000017538

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Sent: 6/5/2020 9:03:55 PM
To: Heatherington, Anne [b6] Plump, Andrew [b6] Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Paul Stoffel [b6] Perala, Mie [b6]
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Subject: Re: Data-Sharing
Flag: Follow up

Anne,
Thanks for your note. As you well know ClinicalTrials.gov (CT.gov) displays summary level data only. A number of concerns have been expressed about CT.gov during the course of ACTIV discussions and several people have argued that the Gates Accelerator system is superior. NIH does not know if this is based on recent experience with CT.gov (as a number of improvements have been made over the last year) or if this is residual from a time when CT.gov did need a significant enhancement. Further we at NIH have not had the opportunity to work with the Gates Accelerator system and so it is difficult for us to ascertain if it represents an advance over CT.gov or not, particularly since trials will still have to be registered in CT.gov. It makes no sense to double the work, unless there is a measurable advantage to do so.

Some folks at NIH have some familiarity with the TransCelerate system, and have indicated it has many positive attributes. However we would need to understand how non TransCelerate members will be granted (controlled) access and more about security features.

I hope that helps. In addition to Chris several folks from CT.gov will join the meeting to answer any questions that may arise.

Best wishes,
Larry

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

On 6/5/20, 4:27 PM, "Heatherington, Anne" <anne.[b6] wrote:

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To: Plump, Andrew <[REDACTED]> b6, Paul Stoffel <[REDACTED]> b6, Heatherington, Anne <[REDACTED]> b6
Cc: Mikael Dolsten MD PhD <mikael.dolsten@nih.gov> b6, Wholley, David (FNIH) [T] <[REDACTED]> b6
Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov> b6, Freire, Maria (FNIH) [T] <[REDACTED]> b6
Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> b6
Subject: RE: Data-Sharing

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Best, Francis

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From: Plump, Andrew <[REDACTED]> b6
Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6, Paul Stoffel <[REDACTED]> b6
Heatherington, Anne <anne.heatherington@nih.gov> b6, Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Mikael Dolsten MD PhD <mikael.dolsten@nih.gov> b6
Subject: Data-Sharing

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Sent: 8/3/2020 11:59:04 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: Re: CLOSE HOLD: FINAL ROLLOUT MATERIALS: ACTIV-2 and -3 Announcements Tomorrow

ok

From: "Myles, Renate (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Monday, August 3, 2020 at 7:58 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> **b6**
Subject: RE: CLOSE HOLD: FINAL ROLLOUT MATERIALS: ACTIV-2 and -3 Announcements Tomorrow

I think you can share the rollout plan and the embargoed media advisory and news releases (1, 2-5). That should be enough.

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> **b6**
Sent: Monday, August 3, 2020 7:55 PM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]> **b6**
Subject: Re: CLOSE HOLD: FINAL ROLLOUT MATERIALS: ACTIV-2 and -3 Announcements Tomorrow

So what do you want me to send to Danielle? The briefing document (7)?

From: "Myles, Renate (NIH/OD) [E]" <[REDACTED]> **b6**
Date: Monday, August 3, 2020 at 7:06 PM
To: Francis Collins [REDACTED] **b6**, Janet Woodcock <[REDACTED]> **b6**, "Wholley, David (FNIH) [T]" <[REDACTED]> **b6**
Cc: "Burklow, John (NIH/OD) [E]" [REDACTED] **b6**, "Wojtowicz, Emma (NIH/OD) [E]" [REDACTED] **b6**, "Seigfreid, Kim (NIH/OD) [E]" <[REDACTED]> **b6**, "Polimeni, Lydia (NIH/OD) [E]" <[REDACTED]> **b6**, "Fritz, Craig (NIH/OD) [E]" [REDACTED] **b6**, "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> **b6**, "Schwetz, Tara (NIH/OD) [E]" <[REDACTED]> **b6**, "Hallett, Adrienne (NIH/OD) [E]" [REDACTED] **b6**, "Higgins, Lauren (NIH/OD) [E]" [REDACTED] **b6**, "Wolinetz, Carrie (NIH/OD) [E]" <[REDACTED]> **b6**, "Parker, Ashley (NIH/OD) [E]" [REDACTED] **b6**, "Brodd, Lauren (NIH/OD) [E]" <[REDACTED]> **b6**, "McManus, Ayanna (NIH/OD) [E]" [REDACTED] **b6**, "Wood, Gretchen (NIH/OD) [E]" [REDACTED] **b6**, "Wholley, David (FNIH) [T]" [REDACTED] **b6**, "Adam, Stacey (FNIH) [T]" [REDACTED] **b6**, "Menetski, Joseph (FNIH) [T]" <[REDACTED]> **b6**, "Meltzer, Abbey (FNIH) [T]" [REDACTED] **b6**, "Gorman, Greta (FNIH) [T]" [REDACTED] **b6**, "Thomas, Ashley (FDA/CDER)" [REDACTED] **b6**
Subject: CLOSE HOLD: FINAL ROLLOUT MATERIALS: ACTIV-2 and -3 Announcements Tomorrow

Hi Francis, Janet and David.

Attached are the final materials for tomorrow's telebriefing; we will have these materials in briefing books for in-person attendees (Collins/Fauci/Woodcock). The media advisory and releases have been issued under embargo. The embargo lifts at 11:00 a.m. ET tomorrow, Tuesday, August 4. Items attached are:

- 1- Rollout Plan
- 2- Run of Show for Media Telebriefing

- 3- Embargoed Media Advisory
- 4- Embargoed Release ACTIV-2
- 5- Embargoed Release ACTIV-3
- 6- Talking Points for Francis Collins
- 7- Briefing Document for ACTIV-2 and ACTIV-3
- 8- QA for ACTIV-2
- 9- QA for ACTIV-3
- 10- Overview of Social Media Event (For Drs. Collins/Fauci only)

Best,
Renate

Renate Myles, MSA

Deputy Director for Public Affairs
Office of Communications and Public Affairs
National Institutes of Health
e **b6**

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 6/5/2020 9:21:23 PM
To: Brennan, Patti (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a15fb17e820c4a418b87b86db1dfd6ff-brennanpf]; Gregurick, Susan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e06fcd4c9c5449fb3151183f1adf35e-greguricksk]; Norris, Andrea (NIH/CIT) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1f8285333385410bb4be4ea63636d1d5-norrisat]
Subject: FW: Data-Sharing

fy

On 6/5/20, 5:15 PM, "Heatherington, Anne" <[REDACTED]> wrote:

Perfect - I have already set the wheels in motion to ensure we are able to address your questions with very positive feedback from the Gates Foundation.

-----Original Message-----

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>
Sent: Friday, June 5, 2020 5:04 PM
To: Heatherington, Anne <[REDACTED]>; Plump, Andrew <[REDACTED]>; Peralá, Míe <[REDACTED]>; Collins, Francis (NIH/OD) [E] <[REDACTED]>; Paul Stoffel <[REDACTED]>
Cc: Mikael Dolsten MD PhD <mikael.[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>; Freire, Maria (FNIH) [T] <[REDACTED]>; Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>
Subject: Re: Data-Sharing

Be advised that this email came from outside Takeda / お知らせ 社外から送信されたメールです

Anne,

Thanks for your note. As you well know Clinical Trials.gov (CT.gov) displays summary level data only. A number of concerns have been expressed about CT.gov during the course of ACTIV discussions and several people have argued that the Gates Accelerator system is superior. NIH does not know if this is based on recent experience with CT.gov (as a number of improvements have been made over the last year) or if this is residual from a time when CT.gov did need a significant enhancement. Further we at NIH have not had the opportunity to work with the Gates Accelerator system and so it is difficult for us to ascertain if it represents an advance over CT.gov or not, particularly since trials will still have to be registered in CT.gov. It makes no sense to double the work, unless there is a measurable advantage to do so.

Some folks at NIH have some familiarity with the TransCelerate system, and have indicated it has many positive attributes. However we would need to understand how non TransCelerate members will be granted (controlled) access and more about security features.

I hope that helps. In addition to Chris several folks from CT.gov will join the meeting to answer any questions that may arise.

Best wishes,
Larry

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

On 6/5/20, 4:27 PM, "Heatherington, Anne" <[REDACTED]> wrote:

I am really happy to co-ordinate this discussion. I note the request for a deeper understanding of the Gates Accelerator as Andy said, do you have other specific requests and I can make sure the answers are provided.

I would plan to include representatives from TransCelerate, Gates Foundation and maybe 2 other pharma for balance.

Anne

-- --Original Message--

From: Plump, Andrew <[REDACTED]>
Sent: Thursday, June 4, 2020 7:38 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Heatherington, Anne <anne.heather[REDACTED]>; Peralá, Míe <[REDACTED]>
Subject: [REDACTED]

LTAB0000016605

Cc: Mikael Dolsten MD PhD <[REDACTED]> b6 wholley, David (FNIH) [T]
< b6 Tabak, Lawrence (NIH/OD) [E] < b6 Freire, Maria (FNIH) [T]
< b6 Austin, Christopher (NIH/NCATS) [E] b6 >
Subject: RE: Data-Sharing

Hi Francis,

Thank you for the rapid and positive response.

Anne has really been leading this with her counterparts across industry. She will assemble the right group and we can find an hour over the next couple of weeks. In addition to a dive into the Gates' data architecture, she or someone from Transcelerate can overview the patient-level data platform.

Larry, if you have specific requests for the meeting please let Anne know directly.

Mie can work with Maria to identify participants help find an hour. Given the agendas in play, hopefully everyone can be a bit flexible and/or find time off hours.

Warm regards,
Andy

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, June 4, 2020 4:03 PM
To: Plump, Andrew <[REDACTED]> b6 Paul Stoffel <[REDACTED]> b6 Heatherington, Anne <[REDACTED]> b6
Cc: Mikael Dolsten MD PhD <[REDACTED]> b6 wholley, David (FNIH) [T]
< b6 Tabak, Lawrence (NIH/OD) [E] b6 Freire, Maria (FNIH) [T]
< b6 Austin, Christopher (NIH/NCATS) [E] <[REDACTED]> b6
Subject: RE: Data-Sharing

Be advised that this email came from outside Takeda / お知らせ 社外から送信されたメールです

Hi Andy,

Thanks for your leadership on these critical data sharing issues -- and yes, a group of us from NIH/FNIH would very much like to meet with you, Anne, and any others that you think would assist the conversation. I have already asked my principal Deputy, Dr. Larry Tabak, to assemble the right NIH group to take part in this conversation, and I will count on David to figure out who should attend from FNIH.

One of the items that I know the group will want to know more about is the Gates Accelerator -- it's been hard to get a sense of the architecture and ease of use. Is there a beta test model available that we could try out?

Best, Francis

-----Original Message-----

From: Plump, Andrew <[REDACTED]> b6
Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Paul Stoffel <[REDACTED]> b6
Heatherington, Anne <[REDACTED]> b6
Cc: Mikael Dolsten MD PhD <[REDACTED]> b6 wholley, David (FNIH) [T]
< b6
Subject: Data-Sharing

Hi Francis and Paul,

Terrific ACTIV leadership meeting yesterday. Remarkable progress.

Following up on the HEVER dialogue on data-sharing. I know you are fully on board with the need for essentially real-time data sharing of emerging clinical trial data, and there is a team that has identified a framework that should work for the NIH. While there may be arcane US government provisions to which we are not aware, the privacy considerations are at least as stringent within industry, and essentially all companies have agreed to the framework Anne presented, so I do not imagine roadblocks.

My suggestion is that Anne and members of the data sharing group meet with you, David, and/or whomever else you would suggestion from NIH/ACTIV to bring you up to speed and figure out a path forward.

Thanks,
Andy

Sent from my iPad

The content of this email and of any files transmitted may contain confidential, proprietary or legally privileged information and is intended solely for the use of the person/s or entity/ies to whom it is addressed. If you have received this email in error you have no permission whatsoever to use, copy,

disclose or forward all or any of its contents. Please immediately notify the sender and thereafter delete this email and any attachments.

From: Wood, Gretchen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=549F390B39D044A885D1E0E1A8F76C1F-WOODGS]
Sent: 4/15/2020 12:44:59 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: Re: Washington Post
Flag: Follow Up

Just did, thanks very much.

From: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> b6
Date: Wednesday, April 15, 2020 at 8:41 AM
To: Gretchen Wood <[REDACTED]> b6
Subject: Re: Washington Post

Have you forced shutdown and rebooted? That is what I needed to do.

From: "Wood, Gretchen (NIH/OD) [E]" <[REDACTED]> b6
Date: Wednesday, April 15, 2020 at 8:40 AM
To: "Myles, Renate (NIH/OD) [E]" <[REDACTED]> b6
Cc: Francis Collins <[REDACTED]> b6 "Burklow, John (NIH/OD) [E]" <[REDACTED]> b6 "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> b6 "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED]> b6
"Parker, Ashley (NIH/OD) [E]" <[REDACTED]> b6 "Wholley, David (FNIH) [T]" <[REDACTED]> b6
"Freire, Maria (FNIH) [T]" <[REDACTED]> b6 "McManus, Ayanna (NIH/OD) [E]" <ayanna.[REDACTED]> b6
Subject: Re: Washington Post

Renate, My MAC is spinning and my iPhone is in Outlook update password reentry. FC is clearing his calendar do as soon as Ashley has the emails he will be able to do this.

Sent from my iPhone

On Apr 15, 2020, at 8:10 AM, Myles, Renate (NIH/OD) [E] <[REDACTED]> b6 wrote:

Okay; working it out.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, April 15, 2020 8:02 AM
To: Myles, Renate (NIH/OD) [E] <[REDACTED]> b6 Burklow, John (NIH/OD) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6
Cc: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> b6 Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6 McManus, Ayanna (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: Washington Post

Yes, definitely!!! My message to you got caught in the Outlook reboot last night, so when I said "tomorrow" I meant today!

From: Myles, Renate (NIH/OD) [E] [b6] >
Sent: Wednesday, April 15, 2020 7:35 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E]
[b6] >; Tabak, Lawrence (NIH/OD) [E] < [b6] Lane, Cliff
(NIH/NIAID) [E] [b6] >
Cc: Wood, Gretchen (NIH/OD) [E] < [b6] Parker, Ashley (NIH/OD) [E]
[b6] Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T]
[b6] >
Subject: RE: Washington Post

Hi Francis:

Any chance you can speak to Carolyn by end of day today? She's pushing for comment today.

Renate

From: Collins, Francis (NIH/OD) [E] < [b6]
Sent: Wednesday, April 15, 2020 4:04 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E]
[b6] >; Tabak, Lawrence (NIH/OD) [E] < [b6] Lane, Cliff
(NIH/NIAID) [E] [b6] >
Cc: Wood, Gretchen (NIH/OD) [E] < [b6] Parker, Ashley (NIH/OD) [E]
[b6] Wholley, David (FNIH) [T] < [b6]; Freire, Maria (FNIH) [T]
< [b6]
Subject: FW: Washington Post

Hi all,

As you can see from Tony's message, he got a green light from WH Comms (Devin O'Malley) for me to talk with Carolyn Johnson tomorrow about ACTIV. Apparently there was no time to discuss this with the Task Force today (they were all focused on economics) but Tony was able to talk with Comms – [b5]
[b5] Tony called me earlier in the evening to make sure that wasn't the case, and I reassured him. Given that, the WH Comms said it was OK to talk with Carolyn, [b5]
[b5]
[b5]

[b5]
[b5]

Renate, can you work with Gretchen to find a good time for me to talk with Carolyn tomorrow?

I'll need to send out that note to ACTIV partners to let them know a press story is coming. That would include industry, academics, and other government participants. I'm ccing Ashley to ask her to work with David Wholley and his team to get me a complete e-mail list. As you know, Dolsten has agreed to be a press contact. No word back yet from Stoffels.

FC

From: Fauci, Anthony (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 14, 2020 9:44 PM
To: Johnson, Carolyn <Carolyn.Johnson@washpost.com>
Cc: Collins, Francis (NIH/OD) [E] <cc [b6]> Lane, Cliff (NIH/NIAID) [E]
[b6]; Billet, Courtney (NIH/NIAID) [E] [b6] Conrad, Patricia
(NIH/NIAID) [E] [b6] >
Subject: RE: Washington Post

Carolyn:

Thanks for the note. I understand that you will be hearing from Francis Collins on the Public Private Partnership (PPP) that we have put together to combine the resources and assets of industry and the academic community that is largely supported by NIH, particularly NIAID in the context of COVID-19. It is the functional equivalent of a National Strategy. We at NIAID and to some extent other institutes are leveraging our vast clinical trials networks that we built for other infectious diseases, particularly, but not exclusively HIV/AIDS, to provide the capacity to conduct clinical trials (NIH-sponsored as well as industry-sponsored) for both vaccines and therapeutics for COVID-19. For your interest, I am attaching a copy (not yet released) of the NIAID Strategic Plan for COVID-19 Research. It is an outline that will be supplemented with an implementation plan.

Best regards,
Tony

From: Johnson, Carolyn <Carolyn.Johnson@washpost.com>
Sent: Tuesday, April 14, 2020 10:23 AM
To: Fauci, Anthony (NIH/NIAID) [E] [b6]
Subject: Washington Post

Dear Tony,
Is there a national strategy at the task force level to coordinate clinical research efforts nationally? We have heard lots of complaints that there isn't a national strategy. I talked to Cliff Lane about this, but we want to give you the chance to respond.
Carolyn

Carolyn Johnson
Washington Post
202-334-6248 (desk)
[b6] (cell)

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 6/5/2020 2:54:06 AM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: Re: Data-Sharing
Flag: Follow Up

Thank you Larry.

From: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 >
Date: Thursday, June 4, 2020 at 10:39:04 PM
To: "Freire, Maria (FNIH) [T]" <[REDACTED] b6 >
Subject: Re: Data-Sharing

Maria,
You have every right to be angry. I am very sorry you were subjected to his prejudice.
Larry

From: "Freire, Maria (FNIH) [T]" <[REDACTED] b6 >
Date: Thursday, June 4, 2020 at 8:33 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 >
Subject: Fwd: Data-Sharing

Larry, I did not copy you or the others on this note to Francis and David but I am furious. The assumption that I am a secretary because I am the only woman copied on the NIH side of the email is downright offensive and it demonstrates that this person does not even have enough sense to research who he is referring to. Nothing anyone can do about his bigotry but this is unbelievable.

From: "Freire, Maria (FNIH) [T]" <[REDACTED] b6 >
Date: Thursday, June 4, 2020 at 7:45:30 PM
To: "Wholley, David (FNIH) [T]" <[REDACTED] b6 > "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6 >
Subject: Fwd: Data-Sharing

María (the secretary) will set this up?! Is he kidding me?!!

From: "Plump, Andrew" <[REDACTED] b6 >
Date: Thursday, June 4, 2020 at 7:38:20 PM
To: "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6 > "Paul Stoffel" <[REDACTED] b6 > "Heatherington, Anne" <[REDACTED] b6 > "Peralá, Mie" <[REDACTED] b6 >
Cc: "Mikael Dolsten MD PhD" <[REDACTED] b6 > "Wholley, David (FNIH) [T]" <[REDACTED] b6 > "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 > "Freire, Maria (FNIH) [T]" <[REDACTED] b6 > "Austin, Christopher (NIH/NCATS) [E]" <[REDACTED] b6 >
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To: Plump, Andrew <[REDACTED]> Paul Stoffel <[REDACTED]> Heatherington, Anne <[REDACTED]>
Cc: Mikael Dolsten MD PhD <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Austin, Christopher (NIH/NCATS) [E] <[REDACTED]>
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Best, Francis

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Sent: Thursday, June 4, 2020 3:29 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Paul Stoffel <[REDACTED]> Heatherington, Anne <[REDACTED]>
Cc: Mikael Dolsten MD PhD <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]>
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